In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: February 20, 2024

LORI PHELAN, on behalf of her minor child, A.P.,	*	PUBLISHED
Petitioner,	*	No. 18-1366V
v.	*	Special Master Nora Beth Dorsey
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Dismissal; Measles-Mumps-Rubella ("MMR") Vaccine; Pediatric Acute Neuropsychiatric Syndrome ("PANS").
Respondent.	*	

Curtis R. Webb, Monmouth, Oregon, for Petitioner.
Jennifer A. Shah, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION[1]

On September 6, 2018, Lori Phelan ("Petitioner"), on behalf of her minor child, A.P., filed a petition for compensation under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 et seq. (2018),[2] alleging that A.P.

[1] Because this Decision contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2018) ("Vaccine Act" or "the Act"). All citations in this Decision to individual sections of the Vaccine Act are to 42 U.S.C.A. § 300aa.

suffered from Pediatric Acute Neuropsychiatric Syndrome ("PANS")[3] as a result of receiving measles-mumps-rubella ("MMR") and/or varicella vaccinations on September 10, 2015.[4] Petition at ¶ 5 (ECF No. 1). Respondent argued against compensation, stating the case was "not appropriate for compensation under the terms of the Vaccine Act." Respondent's Report ("Resp. Rept.") at 2 (ECF No. 14).

After carefully analyzing and weighing the evidence presented in accordance with the applicable legal standards, the undersigned finds Petitioner has failed to provide preponderant evidence that the MMR vaccination caused A.P. to develop PANS. Thus, Petitioner has failed to satisfy her burden of proof under Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, the petition must be dismissed.

I. ISSUES TO BE DECIDED

The issues of diagnosis and causation are in dispute. Regarding diagnosis, the parties dispute whether A.P. has PANS. Joint Pre-Hearing Submission, filed July 14, 2022, at 2 (ECF No. 70). Regarding causation, the parties dispute whether "the MMR vaccine administered to A.P. on September 10, 2015[] caused A.P.'s alleged injury." Id.

II. BACKGROUND

A. Medical Terminology: Pediatric Acute Neuropsychiatric Syndrome ("PANS")

PANS developed out of research and study of another condition, Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections ("PANDAS"), by Dr.

[3] Although the petition defined PANS as "Pediatric Autoimmune Neuropsychological Syndrome," the Joint Submission, experts, and medical literature identified PANS as "Pediatric Acute Neuropsychiatric Syndrome." See Petition at ¶ 5 (ECF No. 1); Joint Pre-Hearing Submission, filed July 14, 2022, at 2 (ECF No. 70); Petitioner's Exhibit ("Pet. Ex.") 33 (Denise Calaprice et al., A Survey of Pediatric Acute-Onset Neuropsychiatric Syndrome Characteristics and Course, 27 J. Child & Adolescent Psychopharmacology 607 (2017)). Therefore, the undersigned will use "Pediatric Acute Neuropsychiatric Syndrome" or PANS throughout this Decision.

[4] In the Joint Submission, Petitioner narrowed her allegations of causation to the MMR vaccine and dropped her prior reference to the varicella vaccine. See Petition at ¶ 5; Joint Pre-Hearing Submission at 1-2. Therefore, this Decision addresses only the MMR vaccine. However, even if Petitioner had alleged that the varicella vaccine was causative, the outcome would be the same, as Petitioner failed to provide preponderant evidence that the varicella vaccine can or did cause PANS in this case.

Susan E. Swedo and others. See, e.g., Pet. Ex. 29;[5] Pet. Ex. 30.[6] PANS is "much broader" than PANDAS in that it includes "not only disorders potentially associated with a preceding infection, but also acute-onset neuropsychiatric disorders without an apparent environmental precipitant or immune dysfunction."[7] Pet. Ex. 30 at 3; see also Pet. Ex. 33 at 3 fig.1 (showing PANS hierarchy).

PANS "is a clinical condition defined by the unusually abrupt onset of obsessive-compulsive symptoms and/or severe eating restrictions and at least two concomitant cognitive, behavioral, or neurological symptoms." Resp. Ex. A, Tab 23 at 1.[8] Additional features may include "separation anxiety[], attention deficit, hyperkinesis, emotional lability and/or depression, irritability, aggressiveness or oppositional behavior, and academic decline." Pet. Ex. 18 at 2.[9] "Associated neurological findings are often present" and "include cognitive impairments, motor or vocal tics, increased sensory sensitivities, choreiform finger movements, deteriorating penmanship, and urinary frequency and/or enuresis." Id.

Further, PANS is "a diagnosis of exclusion," and "[t]he diagnosis of PANS should be made only when 'symptoms are not better explained by a known neurological or medical disorder'" after completion of a "comprehensive diagnostic evaluation." Resp. Ex. A, Tab 23 at 2. The condition is characterized by a "relapsing-remitting course." Pet. Ex. 18 at 2.

Most cases of PANS are thought to be post-infectious in nature, "although no single microbe other than [Group A *Streptococcus*] has yet been consistently associated with the onset of PANS." Pet. Ex. 17 at 6. Commonly associated infections include "upper respiratory infection[s]." Id. Patients should be monitored for infections, particularly "sinusitis and influenza." Pet. Ex. 18 at 2. "[I]nfections should be diagnosed and treated promptly according

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[5] Susan E. Swedo et al., Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections: Clinical Description of the First 50 Cases, 155 Am. J. Psychiatry 264 (1998). This was also filed as Resp. Ex. A, Tab 22.

[6] Susan E. Swedo et al., From Research Subgroup to Clinical Syndrome: Modifying the PANDAS Criteria to Describe PANS (Pediatric Acute-Onset Neuropsychiatric Syndrome), 2 Pediatrics & Therapeutics 1 (2012). This was also filed as Resp. Ex. A, Tab 24.

[7] For a history of PANS and its differences from PANDAS, see, for example, Pet. Ex. 17 at 2-4 (Kiki Chang et al., Clinical Evaluation of Youth with Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS): Recommendations from the 2013 PANS Consensus Conference, 25 J. Child & Adolescent Psychopharmacology 3 (2015)).

[8] Susan E. Swedo et al., Overview of Treatment of Pediatric Acute-Onset Neuropsychiatric Syndrome, 27 J. Child & Adolescent Psychopharmacology 1 (2017).

[9] Michael S. Cooperstock et al., Clinical Management of Pediatric Acute-Onset Neuropsychiatric Syndrome: Part III—Treatment and Prevention of Infections, 27 J. Child & Adolescent Psychopharmacology 594 (2017).

to current standard guidelines. . . . Standard immunizations . . . are encouraged." Id. at 2, 9 ("Children with PANS . . . should receive standard childhood vaccines . . . .").

The diagnostic criteria for PANS is set forth below:

Criterion	Description
I.	Abrupt, dramatic onset of obsessive-compulsive disorder or severely restricted food intake
II.	Concurrent presence of additional neuropsychiatric symptoms, with similarly severe and acute onset, from at least two of the following seven categories (see text for full description):
	1. Anxiety
	2. Emotional lability and/or depression
	3. Irritability, aggression and/or severely oppositional behaviors
	4. Behavioral (developmental) regression
	5. Deterioration in school performance
	6. Sensory or motor abnormalities
	7. Somatic signs and symptoms, including sleep disturbances, enuresis or urinary frequency
III.	Symptoms are not better explained by a known neurologic or medical disorder, such as Sydenham chorea, systemic lupus erythematosus, Tourette disorder or others.
	Note: The diagnostic work-up of patients suspected of PANS must be comprehensive enough to rule out these and other relevant disorders. The nature of the co-occurring symptoms will dictate the necessary assessments, which may include MRI scan, lumbar puncture, electroencephalogram or other diagnostic tests.

Pet. Ex. 30 at 4 tbl.2.

The first criterion,[10] "[a]brupt, dramatic onset of obsessive-compulsive disorder [("OCD"),] . . . must be sufficiently frequent and intense to meet [Diagnostic and Statistical Manual of Mental Disorders ("DSM")]-IV criteria[11] for OCD and must cause significant distress and interference in the child's activities at home, at school[,] and with peers." Pet. Ex. 30 at 3. The DSM-IV sets forth four criteria for the definition of obsessions:

1. Recurrent and persistent thoughts, impulses, or images that are experienced, at some time during the disturbance, as intrusive and inappropriate and that cause marked anxiety or distress.
2. The thoughts, impulses, or images are not simply excessive worries about real-life problems.

[10] Because the experts agree A.P. did not have "severely restricted food intake," it is not addressed here. See Tr. 118, 163.

[11] For the complete DSM-IV criteria for OCD, see Pet. Ex. 44 at 4-5 (Substance Abuse & Mental Health Servs. Admin., Ctr. for Behav. Health Stat. & Quality, Impact of the DSM-IV to DSM-5 Changes on the National Survey on Drug Use and Health (2016)). Only certain pages of the report were filed. Additionally, this exhibit includes the criteria set forth in the DSM-V.

3. The person attempts to ignore or suppress such thoughts, impulses, or images or to neutralize them with some other thought or action.
4. The person recognizes that the obsessional thoughts, impulses, or images are a product of his or her own mind (not imposed from without as with thought insertion).

Pet. Ex. 44 at 4 tbl.3.13. The DSM-IV also sets forth two criteria for the definition of compulsions:

1. Repetitive behaviors (e.g., hand washing, ordering[,] checking) or mental acts (e.g., praying, counting, repeating words silently) that the person feels driven to perform in response to an obsession, or according to the rules that must be applied rigidly.
2. The behaviors or mental acts are aimed at preventing or reducing distress or preventing some dreaded event or situation. However, these behaviors or mental acts either are not connected in a realistic way with what they are designed to neutralize or prevent or are clearly excessive.

Id.

Next, there must be at least two additional neuropsychiatric symptoms from the list of categories in the PANS criteria table above.[12] Pet. Ex. 30 at 4 tbl.2. The onset of these symptoms must also be severe and acute. Id.

To establish the diagnosis, a comprehensive diagnostic evaluation must be performed "to rule out all other disorders." Pet. Ex. 30 at 6. The evaluation should include a "complete medical history and thorough physical and neurological examination," and may also include "laboratory tests on blood and cerebrospinal fluid, an electroencephalogram, [magnetic resonance imaging ("MRI")] scan, or other diagnostic tests, as indicated." Id. A throat culture for Group A *Streptococcus* or other tests to identify an underlying infection may be done. Id.

Children with PANS may be "extremely ill, with extreme compulsions (licking shoes, barking), motor and phonic tics (whooping, wringing hands), behavioral regression, and terrifying episodes of extreme anxiety or aggression." Pet. Ex. 17 at 3. Due to the extreme presentation, the "behavioral manifestations often prompt rapid referral to psychological or

[12] For a detailed description of each category, see Pet. Ex. 30 at 4-6.

psychiatric services." Id. Differential diagnoses may include OCD, anorexia nervosa, Tourette syndrome,[13] Bipolar disorder,[14] Sydenham chorea,[15] and others. Id. at 3, 3 tbl.2.

B. Procedural History

Petitioner filed her petition along with medical records and an affidavit on September 6, 2018. Petition; Pet. Exs. 1-4. Petitioner filed additional medical records on February 8, 2019. Pet. Ex. 5-10. Respondent filed his Rule 4(c) Report, arguing against compensation, on June 11, 2019. Resp. Rept. at 2.

Thereafter, Petitioner filed updated medical records on August 12, 2019 and an expert report from Dr. Marcel Kinsbourne on December 9, 2019. Pet. Exs. 11-15. Respondent filed an expert report from Dr. Donald L. Gilbert on March 9, 2020. Resp. Ex. A. The case was then reassigned to the undersigned on March 13, 2020. Notice of Reassignment dated Mar. 13, 2020 (ECF No. 26). Petitioner filed an expert report from Dr. Kinsbourne on December 4, 2020, and Respondent filed an expert report from Dr. Gilbert on February 5, 2021. Pet. Ex. 32; Resp. Ex. C.

The undersigned held a status conference on March 30, 2021. Order dated Mar. 30, 2021 (ECF No. 44). During the conference, Petitioner requested an entitlement hearing, which was set to begin in August 2022. Id.; Prehearing Order dated Apr. 30, 2021 (ECF No. 46). Petitioner filed updated medical records on January 14, 2022. Pet. Exs. 42-43.

An entitlement hearing was held on August 24 and 25, 2022. Order dated Aug. 25, 2022 (ECF No. 73). Petitioner, Dr. Kinsbourne, and Dr. Gilbert testified. Transcript ("Tr.") 3. Thereafter, both parties filed additional evidence and post-hearing briefing from September 2022 to June 2023. Pet. Exs. 45-47; Resp. Exs. D-E; Pet. Post-Hearing Brief ("Br."), filed Jan. 4,

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[13] Tourette syndrome is "a syndrome comprising both multiple motor and one or more vocal tics, occurring over a period of at least [one] year, at least intermittently but sometimes as frequently as many times daily. Obsessions, compulsions, hyperactivity, distractibility, and impulsivity are often associated." Gilles de la Tourette Syndrome, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=110656 (last visited Feb. 6, 2024).

[14] Bipolar disorder is a "mood disorder[] characterized by a history of manic, mixed, or hypomanic episodes, usually with concurrent or previous history of one or more major depressive episodes." Bipolar Disorders, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=71075 (last visited Feb. 6, 2024).

[15] Sydenham chorea is "an acute, generally self-limited, neurologic disorder seen most often in children between the ages of [five] and 15 years" and "is characterized by involuntary movements that gradually become severe and affect all motor activities, including gait, arm movements, and speech." Sydenham Chorea, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=65141 (last visited Feb. 6, 2024). Additionally, "[a] mild psychic component is usually present" and "may be limited to one side of the body (hemichorea) or may take the form of muscular rigidity (paralytic chorea)." Id.

2023 (ECF No. 91); Resp. Post-Hearing Br., filed Mar. 31, 2023 (ECF No. 96); Pet. Reply Br., filed June 1, 2023 (ECF No. 104).

This matter is now ripe for adjudication.

C. Factual History

1. Stipulated Facts

The parties agreed that A.P. was four years old when she received an MMR vaccination on September 10, 2015. See Joint Submission at 1. They further agreed that the vaccine "is recognized on the Vaccine Injury Table" and "was administered in the United States." Id.

2. Summary of Medical Records[16]

In addition to the above stipulations, the following is a summary of the medical records.

a. Pre-Vaccination Medical History

A.P. was born at 37.6 weeks gestation on March 5, 2011. Pet. Ex. 6 at 9. A.P. weighed seven pounds, eight ounces at birth and her Apgar scores were eight and nine at one and five minutes, respectively. Id. at 9, 23. She had no apparent significant medical problems at birth. See generally id. at 1-57. At the hospital, A.P.'s mother declined consent for A.P.'s birth dose of hepatitis B vaccine, noting that she would follow up at the doctor's office. Id. at 22. A.P.'s early medical records are largely unremarkable, with the exception of periodic complaints of coughing, congestion, and fever. See Pet. Ex. 7 at 12-23; Pet. Ex. 8 at 2-4. A.P. received her first MMR vaccination on October 8, 2013. Pet. Ex. 3 at 10; Pet. Ex. 7 at 4, 39. No adverse reaction was noted following this vaccination. See Pet. Ex. 7 at 39.

In February of 2015, A.P. saw Dr. John Bisacco for fever and cough. Pet. Ex. 8 at 4. He noted that she was "sick frequently" and used a nebulizer. Id.

On July 27, 2015, A.P. saw Dr. Lisa Meehan for four days of nasal congestion and cough, with some skin lesions and a history of eczema. Pet. Ex. 3 at 3. She was diagnosed with exanthema (a non-specific rash) and upper respiratory infection. Id. at 4. She was treated symptomatically and told to return if symptoms worsened or did not improve within three-to-five days. Id.

On August 27, 2015, A.P. saw Dr. Mitsu Kee at Mid-Suffolk Pediatric Associates for a complaint of a 101° fever for two days and nasal congestion. Pet. Ex. 3 at 6. She was diagnosed

[16] This summary is taken from Respondent's Rule 4(c) Report, as the undersigned finds it to be an accurate representation of the medical records. See Resp. Rept. at 2-11.

with acute otitis media[17] of the right ear and a viral syndrome. Id. Four days later, on August 30, 2015, A.P. presented to Dr. Faiz Ahmad at PM Pediatrics of Seldon with continued complaints of fever for the past five days, including a temperature of 101.6°, decreased appetite, coughing, and wheezing. Id. at 80. Dr. Ahmad noted that A.P.'s fever was continuing and not improving. Id. He prescribed acetaminophen and Benadryl with instructions to follow up with her primary care physician if she did not improve within 48 hours. Id.

b. Date of Vaccination: September 10, 2015

Ten days later, on September 10, 2015, A.P. had a four-year-old well-child exam with Dr. Kee. Pet. Ex. 3 at 9. At that time, she received MMR and varicella (Varivax) vaccines. Id. at 10. Dr. Kee noted that A.P.'s mother (Petitioner) deferred diphtheria-tetanus-acellular pertussis ("DTaP") and polio vaccines, but was aware that A.P. would need to return for her five-year vaccines before starting kindergarten. Id. Dr. Kee noted that A.P. was doing well at home, with a normal developmental assessment, physical examination, and urinalysis. Id. at 8-10. Petitioner completed a patient questionnaire that day and in response to the question "[d]oes the child or a family member currently living in the home have cancer, leukemia, AIDS[,] or any other immune system problem?" indicated that another family member living in the home had "PANDAS, PANS, autoimmune [disorder]," but did not indicate which family member. Id. at 78.

c. Post-Vaccination Medical History

A.P. next presented to a health care provider three months later, on December 1, 2015, for complaints of a sore throat. Pet. Ex. 3 at 83. She was seen by Dr. Melanie O'Neill at Stat Health Immediate Care ("Stat Health") and was diagnosed with strep throat and treated with amoxicillin. Id. At that time, there was no mention of behavioral or other problems. Id.

Two weeks later, on December 14, 2015, A.P. saw Physician Assistant ("PA") Jennifer Fincke, at Stat Health for complaints of a fever. Pet. Ex. 3 at 84. She was diagnosed with an unspecified viral infection and given instructions to take Motrin and Tylenol for fever and pain control. Id. Again, there was no mention of behavioral or other problems. Id. Two days later, on December 16, 2016, A.P. saw Nurse Practitioner ("NP") Lillian Lawton with complaints of fever, cough, and decreased appetite. Id. at 12. Nurse Lawton diagnosed A.P. with acute suppurative otitis media of the left ear and a viral upper respiratory infection, and prescribed antibiotics and symptomatic treatment. Id. at 12-13. There was no mention of behavioral or other problems. Id.

A.P. returned to Dr. Kee on January 22, 2016 for a history of fever, nasal congestion, cough, and runny nose. Pet. Ex. 3 at 15. A.P. was diagnosed with sinusitis and prescribed antibiotics. Id. at 16. Dr. Kee noted that Petitioner requested titers for tetanus-diphtheria-acellular pertussis ("Tdap") in advance of her five-year vaccines. Id. For the first time, almost four-and-one-half months after the MMR vaccination, Dr. Kee noted that Petitioner reported

[17] Otitis media is the "inflammation of the middle ear." Otitis Media, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=95455 (last visited Feb. 6, 2024).

noticing behavior changes in A.P. stating, "per [Petitioner] [MMR]/varivax had noticed then b[e]havior changes/irritable sister [has] autoimmune mom will call in summer for tit[ers]." Id.

On April 11, 2016, A.P. presented to Dr. Meehan with complaints of nasal congestion, cough, earache, and a runny nose. Pet. Ex. 3 at 17. She was diagnosed with possible sinusitis and an upper respiratory infection and she was prescribed antibiotics. Id. at 18.

Approximately one month later, on May 6, 2016, A.P. returned to Dr. Kee for complaints of urinary frequency, nasal congestion, and sneezing. Pet. Ex. 3 at 20. Dr. Kee also noted complaints that A.P. was "acting fussy" for one week. Id. At this time, Dr. Kee noted, "[a]nxiety OCD this week, mom showed me vide[o] re MMR had [anxiety] crying [five] [d]ays after vaccine sister has PANDA[S] re autoimmune issues presented with anxiety. [Difficult separation] issues this week with dance[,] school, [and] crying." Id. A.P. was diagnosed with allergic rhinitis, urinary urgency, and behavioral issues and was to see a specialist regarding the behavioral issues. Id. at 22. Dr. Kee further noted that Petitioner was "concerned re due [five] year old vaccines will check with specialist if unable [to obtain] sooner appt will check tit[ers]." Id.

A.P. returned to Dr. Kee on May 12, 2016, with reports of urinary frequency at school and at night, and separation anxiety relating to school and dance. Pet. Ex. 3 at 24. Petitioner reported A.P. did not have previous separation anxiety and that A.P.'s sibling had a "history of anxiety/autoimmune issues/[PANDAS]." Id.

On May 19, 2016, A.P. had an initial consultation with Dr. Howard J. Balbi, Director of Pediatric Infectious Disease at the Center for Pediatric Specialty Care. Pet. Ex. 3 at 87. Dr. Balbi noted that Petitioner, A.P.'s mother, reported that A.P.

> recently developed a severe separation anxiety and increased urgency over the past three weeks. The mother feels that these symptoms have coincided with the start of [A.P.'s] allergy season. She states that she normally is very independent but now she does not want to go to school and even at home, she does not want to be anywhere other than by the mother's side. . . . Mother states that [A.P.'s] [nine]-year-old sister developed PANS at the age of [six], secondary to Coxsackie virus. The mother states that her symptoms started very similar to this and she is concerned that [A.P.] is also developing PANS.

Id. A.P.'s mother filled out a new patient intake form for Dr. Balbi, indicating that A.P. had "sudden severe separation anxiety in last [two] weeks, a lot of fears (unusual), has been coughing since allergy season began." Pet. Ex. 10 at 9.

Dr. Balbi also noted that Petitioner reported A.P. had separation anxiety in the "fall of last year after receiving the . . . MMR booster[]. It did resolve after about a month." Pet. Ex. 3 at 87. Dr. Balbi added that "[i]n addition to the separation anxiety and frequency that she is having, she also has noted some sensory sensitivity issues such as she is unable to tolerate the sun and the mother has even had to remove the tags from her clothing because it is bothering her. . . . Again this has all taken place over the past three weeks." Id. Assessment was "increased

frequency and separation anxiety." Id. at 88. Dr. Balbi concluded that "[s]ince this is an acute episode, I think PANS is unlikely," but ordered additional blood work and placed A.P. on an antibiotic to see if she would have any improvement on antibiotics "as can be seen with PANS." Id. Allergy testing done on June 7, 2016 was positive for dust mites, tree mix, grass mix, ragweed mix, and other environmental antigens. Pet. Ex. 4 at 165.

On June 9, 2016, A.P. returned to Dr. Balbi for evaluation of separation anxiety and increased urinary urgency. Pet. Ex. 3 at 89. Dr. Balbi further noted that "[t]he mother was concerned about PANS as she has an older child that has been diagnosed with this. While the history was not consistent with this, [] we did do blood work to try to rule this out." Id. A.P.'s mother also reported that since their last visit to Dr. Balbi, A.P. was started on medications for allergies, which improved her allergies and her symptoms of anxiety and urinary frequency. Id. He reported that her bloodwork showed a negative Epstein-Barr virus ("EBV") serology, negative Coxsackie virus titers, normal erythrocyte sedimentation rate ("ESR") and C-reactive protein, normal Immunoglobulin ("Ig") G, A, and M, but significantly elevated IgE, consistent with allergies. Id. Dr. Balbi concluded that A.P. had "improving separation anxiety and allergies" and that "[s]he has been seen by her allergist who did do allergy testing and PANS is much less likely in this situation." Id. at 90.

In July 2016, A.P. saw Dr. Michael Elice, a pediatrician at AIM Integrative Medicine who advertises that he treats conditions such as autism spectrum disorders, immune and metabolic dysregulation, and PANDAS. Pet. Ex. 4 at 3. A.P. presented with complaints of sudden onset separation anxiety and urinary frequency. Id. According to Dr. Elice, Petitioner reported that some early symptoms started after her MMR vaccination, coincident with fall seasonal allergies. Id. at 3. He noted Petitioner reported A.P.'s

> [s]eparation was severe and lasted a month and then faded away going back to her normal self. She had a few ear infections/viruses through the winter without any anxiety symptoms. In April, she had obvious allergic eyes and nose which coincided with severe separation anxiety, refusal to go to school[,] or leave mom even in the home. Antihistamine at night and day helped allergy symptoms but "PANDAS" symptoms persisted. She also had a [two] week episode of urinary symptoms with urgency, not completely emptying her bladder without any abnormalities on [urinalysis]. She has developed sensory sensitivities [] like walking on grass now hurts her. Mom is anxious to diagnose and treat this problem since her older sister has PANS.

Id.

Dr. Elice noted that A.P. had tics and stimulations; was aggressive towards others; had tantrums; was cranky and irritable; had rituals, phobias, and fears; was resistant to change; had anxiety and panic; could not tolerate bright sun; refused to go outside; had eye-blinking; had difficulty tolerating heat and cold; was afraid of new things; was temperamental; and was obsessed on specific activities. Pet. Ex. 4 at 4. On physical examination, A.P. had burning, tearing, and red puffy eyes; light sensitivity; nose and throat itchiness; and stuffiness, postnasal

drip, and sinus pain. Id. at 6-7. She also had red ears, itchy skin, and eczema. Id. Dr. Elice assessed A.P. with allergic rhinitis due to mold, animal hair, and dander. Id. at 9.

A.P. visited Dr. Elice on August 23, 2016 with continued anxiety. Pet. Ex. 4 at 10. Dr. Elice suggested that A.P.'s lab results indicated an intestinal or pancreatic dysfunction, loss of cholesterol in her stool, and a lack of probiotics. Id. at 17. She was prescribed antibiotics (azithromycin[18] and metronidazole),[19] supplements (acetyl L-carnitine, vitamin C, methyl B12, zinc picolinate, orthobiotic), and told to follow up in six to eight weeks. Id. Two days later, A.P. saw Dr. Kee for a red, itchy rash and was treated with Benadryl and hydrocortisone. Pet. Ex. 3 at 28. A.P.'s labs from September 9, 2016 indicated that she had an appropriate immune response to MMR, varicella, and tetanus vaccines. Pet. Ex. 4 at 169-71.

On October 8, 2016, A.P. saw Dr. Kee for a fever, sore throat, and stomach ache. Pet. Ex. 3 at 30. She tested negative for strep and was encouraged to take fever and pain control over-the-counter medications. Id. at 32. Four days later, A.P. presented to Nurse Lillian Hernandez for a five-year-old well-child exam. Id. at 33. Nurse Hernandez noted A.P. was doing well at home, had a good appetite, and was sleeping well. Id. She further noted that A.P.'s parents had no current concerns or issues, and that there were no developmental issues. Id. Nonetheless, polio and DTaP vaccinations were withheld. Id.

On October 19, 2016, A.P. followed up with Dr. Elice. Pet. Ex. 4 at 18. A.P. stopped the antibiotics due to abdominal pain and had reported only a slight improvement in separation anxiety and tics. Id. Dr. Elice noted that A.P. was still waking up for school in "fight/flight mode," but was able to work through it and was doing well at school but avoiding outside activities unless her mother was present. Id. Dr. Elice diagnosed A.P. with a parasite infection and ordered her to restart the metronidazole antibiotics, with a probiotic to be given four hours apart. Id. at 25.

A.P. saw Dr. Elice next on December 20, 2016. Pet. Ex. 4 at 26. According to Petitioner, "[A.P.'s] symptoms calmed down when the weather changed, not when she took metronidazole, she had no separation anxiety, [and] went to school without any problem." Id. Petitioner apparently reported that at that time, A.P. was "so typical that she wouldn't have ever consulted" Dr. Elice. Id. She also stated that two weeks prior, A.P. had a fever, sinus congestion, and cough. Id. She was treated for a sinus infection, but her fever persisted. Id. A.P. returned to the doctor and was told she had a viral illness and that her influenza swab was negative. Id. During this time, A.P. "regressed back to baby talk, more clingy but not as bad as

[18] Azithromycin is "an azalide antibiotic . . . that inhibits bacterial protein synthesis, effective against a wide range of gram-positive, gram-negative, and anaerobic bacteria; used in the treatment of mild to moderate infections caused by susceptible organisms." Azithromycin, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=5244 (last visited Feb. 6, 2024).

[19] Metronidazole is "an antiprotozoal and antibacterial effective against obligate anaerobes." Metronidazole, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=31073 (last visited Feb. 6, 2024).

before." Id. She also noted that A.P. was angry, had a decreased appetite, and was food sensitive again. Id. Dr. Elice's assessment was a mitochondrial disorder and viral syndrome, and he recommended not changing anything at that time as A.P. appeared to be recovering. Id. at 44.

A.P. returned to Dr. Elice on January 18, 2017 because she had not improved. Pet. Ex. 4 at 34. A.P. still had separation anxiety, urinary frequency, nocturnal awakening, phobias and worries, and food sensitivities. Id. Several days prior, she had a fever of 102 degrees, was lethargic, and had a cough, but her pediatrician was unable to identify anything wrong. Id. A.P. was sleeping with her mother in bed and obsessed that kindergarten was too hard, but was able to remain in school once her mother left. Id. Dr. Elice assessed A.P. with sinusitis and PANDAS, prescribed azithromycin and Pulmicort,[20] and ordered additional labs. Id. at 41.

On February 8, 2017, A.P. saw Dr. Elice again for continued issues with separation anxiety, including difficulty getting to school, although she was able to get through school once she was there. Pet. Ex. 4 at 42. Additionally, A.P.'s mother reported that A.P. became aggressive after becoming annoyed with another child on the school bus, was using more baby talk, and mouthing inedible objects. Id. She was also doing well academically. Id. Dr. Elice assessed her with low proline, threonine, and tryptophan, elevated IgE, zinc deficiency, low carnitine, mitochondrial disorder, PANDAS, vitamin D deficiency, and a parasite infection. Id. at 49. The plan was to increase protein in her diet, add 5-HT and azithromycin, continue the metronidazole, and to use the Pulmicort nebulizer every 12 hours to see if the steroid adrenal effect helped with her behavior. Id. at 49.

The following month, on March 16, 2016, A.P. returned to Dr. Elice for follow up at which time Petitioner reported that A.P. was leaving the house and going to school fine without any baby talk. Pet. Ex. 4 at 51. She was assessed with PANDAS and allergic rhinitis. Id. at 59. Since she was doing well, Dr. Elice declined to pursue antimicrobials, but added cyproheptadine[21] to control her itching, which historically worsened in the spring. Id.

From May through September 2017, A.P. was seen by various health care providers for complaints of fever, ear pain, abdominal pain, diarrhea, and upper respiratory infection symptoms. See Pet. Ex. 3 at 49-55. On September 18, 2017, Petitioner also reported continued separation anxiety, including one episode the previous week involving screaming about leaving the house for school. Pet. Ex. 4 at 60. Other than that, however, Dr. Elice noted that she had no other regression into "typical PANDAS/PANS symptoms." Id. When she returned to Dr. Elice

[20] Pulmicort (budesonide) is used "to treat asthma" and "allergic rhinitis and other inflammatory nasal conditions." Budesonide, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=7201 (last visited Feb. 6, 2024).

[21] Cyproheptadine hydrochloride is "an antihistamine (H1 receptor antagonist) with sedative, anticholinergic, serotonin-blocking, and calcium channel-blocking effects; used in the treatment of allergic rhinitis, allergic conjunctivitis, and cutaneous and systemic manifestations of allergic reactions . . . ." Cyproheptadine Hydrochloride, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=12240 (last visited Feb. 6, 2024).

on September 16, 2017, he was concerned that A.P. may have inflammatory bowel disease. Id. at 64. However, her respiratory and behavioral symptoms were improving by the time she returned on October 12, 2017. Id. By that time, she was sleeping in her own bed, did not have "meltdowns" on Sunday nights before school, and had made friends. Id. at 68. Dr. Elice diagnosed her with clostridium difficile colitis ("*C. difficile*")[22] and noted that she should continue the metronidazole and watch for inflammatory bowel disease. Id. at 75. He also filled out a school immunization medical exception form on that day for polio (IPV or OPV) and Tetanus, Diphtheria, Pertussis (DTaP, DTP, Tdap), stating A.P. had a diagnosis of "mitochondrial disorder – inability to detoxify toxic adjuvants in these vaccines." Id. at 187.

In November and December 2017, A.P. returned to Dr. Kee with complaints of minor ailments, including cough, upper respiratory infection, fever, earache, nasal congestion, headache, and decreased appetite. Pet. Ex. 3 at 57-60. In February 2018, A.P. had additional labs done, including a metabolic panel, Coxsackie, streptolysin O, complete blood count, and Lyme titers. Pet. Ex. 4 at 99. Her results were normal and/or non-contributory. Id. at 112. Her IgE level remained elevated. Id. at 103. A.P. returned to Dr. Elice on March 19, 2018, and Petitioner reported that A.P. was doing well in first grade, with no social issues and only a flare up when she had *C. difficile*. Id. at 76. Dr. Elice ordered monitoring for allergic triggered regression and assessed her with PANDAS, allergy to pollen, and vitamin D deficiency. Id. at 83. On April 27, 2018, A.P. saw Dr. Cheng for a six-year physical. Pet. Ex. 3 at 65. Her history reported no reactions to previous vaccines, and that she was doing well at home and school with no current concerns or issues. Id. He further noted that A.P. was seeing Dr. Elice for autoimmune issues and had a note for medical exemption for vaccines. Id.

3. Petitioner's Affidavit and Testimony

a. Affidavit

Petitioner is the mother of A.P. Pet. Ex. 1 at ¶ 2. In 2014, A.P., at three years of age, began preschool and "had a remarkable first year, both academically and socially." Id. at ¶¶ 7-8. Prior to this, A.P. attended Mommy and Me programs, separation classes at two years of age, and participated in a jungle gym program. Id. at ¶ 6. She also "had no delays, deficits[,] or issues of any kind, and achieved all [of] her developmental milestones within the normal range." Id. at ¶ 5.

In September 2015, A.P. returned to school and "attended her first week eagerly and willingly." Pet. Ex. 1 at ¶ 9. "After [two] weeks into the school year, [Petitioner] saw a sudden and dramatic change in [A.P.'s] behavior and mood." Id. at ¶ 10. "This was [seven to eight] days after her September 10, 2015 well visit, where she received her MMR booster and [v]aricella booster." Id. at ¶ 11. A.P. "would wake up crying every morning saying she was scared but could not identify what scared or worried her." Id. at ¶ 12. "She showed sudden

[22] *C. difficile* is "a species that is part of the normal colon flora in infants and some adults; it produces a toxin that can cause pseudomembranous enterocolitis in patients receiving antibiotic therapy." Clostridium Difficile, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=65630 (last visited Feb. 6, 2024).

extreme sensory sensitivities and could no longer tolerate certain clothing. She would cry and say it hurt her or bothered her. She would cry if [Petitioner] tried to do her hair, saying it was too loose or too tight." Id. at ¶ 13. A.P. also "seemed extremely uncomfortable in her own skin," "displayed extreme episodes of separation anxiety" when going to school, "began showing signs of urinary frequency" that resulted in sleep disturbances, and displayed OCD tendencies when engaging in activities. Id. at ¶¶ 14-18. Petitioner averred A.P. "suddenly appeared to be altered in some way." Id. at ¶ 19.

Due to these symptoms, "[Petitioner] believed that [A.P.] was experiencing an onset of PANS." Pet. Ex. 1 at ¶ 20. Petitioner had prior experience with this condition since A.P.'s older sister, S.P., was diagnosed with PANS at six years of age. Id. at ¶ 21. Petitioner began to treat A.P. with protocols that helped S.P., which included vitamins, supplements, and anti-inflammatories, as well as an adjusted diet. Id. at ¶¶ 22-24.

Petitioner contends A.P.'s onset and flare up lasted four to five months. Pet. Ex. 1 at ¶ 25. By January 2016, A.P.'s symptoms decreased in severity, although "she did not return to baseline." Id. A.P.'s symptoms "heightened" in April 2016 due to allergy season. Id. at ¶¶ 26-27. "[A.P.] began to regress and was debilitated once again with extreme anxiety, urinary frequency urges, sleep disturbances[,] and sensory issues." Id. at ¶ 28. At this time, Petitioner reached out to Dr. Elice, a PANS specialist, who "concluded that pollen was a huge trigger that [led] to [A.P.'s] flare up[,] suggested [A.P.] use a custom-made nasal spray," and encouraged a low histamine diet. Id. at ¶¶ 29-31. Petitioner averred that A.P. continued to have flare ups over the next two years, or as of September 5, 2018, the date in which she executed her affidavit. Id. at ¶ 34.

b. Hearing Testimony

At the hearing, Petitioner testified about the changes in A.P. that she saw following A.P.'s MMR vaccination on September 10, 2015, at four years of age. In the 2014 to 2015 school year, before vaccination, A.P. attended preschool three days per week from 12:00 p.m. until 2:30 p.m. Tr. 7. She did well that school year. Tr. 8. A.P. loved playing outside and was never anxious. Tr. 10. Seven to eight days after vaccination, "A.P. became a totally different child." Tr. 11. She could not tolerate her clothing and was very sensitive. Tr. 11-12. She urinated every 15 minutes. Tr. 12. She woke up terrified in the morning and cried hysterically when she was dropped off at preschool. Tr. 12-13. Petitioner immediately thought A.P. had PANS, a disorder suffered by A.P.'s older sibling, S.P., that had "a very similar presentation," but occurred after illness (coxsackievirus) and not vaccination. Tr. 15, 21-22.

Petitioner described the progression of A.P.'s illness. She stated that A.P.'s illness had "dialed down" by December 2015. Tr. 17-19. A.P. had an exacerbation in April 2016, which Petitioner attributed to pollen exposure. Tr. 19-20. Petitioner sought treatment from a specialist, Dr. Elice, who first saw A.P. in July 2016. Tr. 20-21, 24. Petitioner testified that Dr. Elice

found A.P. "presented . . . like a PANDAS/PANS child" at that visit.[23] Tr. 24. Dr. Elice treated A.P. for environmental allergies with a custom intranasal spray and low histamine diet. Tr. 25-26.

Petitioner noted the Fall of 2016 and beginning of kindergarten was very difficult for A.P. Tr. 28. She had a loose tooth, which was another trigger, and flare ups, described by Petitioner as OCD, where A.P. was fixated on certain things like turtles. Tr. 28-32. A.P. had intrusive thoughts ("sticky thoughts"), she obsessed over her artwork, and she had urinary frequency and insomnia. Tr. 32-36.

At the time of the entitlement hearing, A.P. was 11 years old. Tr. 38. She continued to have anxiety, insomnia, and OCD. Tr. 39. A.P.'s family would make adjustments so that A.P. could participate in soccer. Tr. 40. For example, A.P. would stay indoors during soccer season, except for soccer games. Tr. 40. A.P. continued to also have flares with triggers (allergies, loose teeth, and illnesses). Tr. 41-45.

On cross-examination, Petitioner was questioned about the onset of A.P.'s condition. According to Petitioner, the onset of A.P.'s PANS was characterized by intrusive thoughts, baby talk, and developmental regression that began about seven to eight days after the MMR vaccination on September 10, 2015. Tr. 63. Petitioner agreed that her affidavit, dated September 5, 2018, did not indicate intrusive thoughts, developmental regression, or baby talk beginning seven to eight days after vaccination. Tr. 64-65; see Pet. Ex. 1 at ¶¶ 10-17 (indicating changes in A.P. occurred seven to eight days post-vaccination and included being scared and worried, "sudden extreme sensory sensitivities," "extreme episodes of separation anxiety," "[s]udden sleep disturbances," and others).

A.P.'s medical records show that prior to vaccination, on August 30, 2015, Petitioner took A.P. to the doctor because she had a fever for five days; however, Petitioner did not recall the visit.[24] Tr. 70; Pet. Ex. 3 at 80. Petitioner took A.P. to urgent care on December 1, 2015[25] with complaints of a sore throat. Tr. 71; see Pet. Ex. 3 at 83. Petitioner did not recall this visit. Tr. 72. Petitioner also did not recall taking A.P. to the physician on December 14 and 16, 2015. Id. Although she did not recall these visits, she explained that she did not report A.P.'s ongoing behavioral concerns to physicians during these visits because similar complaints in the past were always dismissed and it was extremely frustrating to not have the support of the medical

[23] Dr. Elice's records do not show that he diagnosed A.P. with PANDAS or PANS at this visit. See Pet. Ex. 4 at 9. His assessments included "[a]llergic rhinitis due to mold" and "[a]llergic rhinitis due to animal (cat) (dog) hair and dander." Id.

[24] The correct date of this visit was August 30, 2015, not August 3, 2015 as indicated in the transcript. Tr. 70; Pet. Ex. 3 at 80.

[25] A.P.'s medical records do not show that she received any medical care from the date of vaccination, September 10, 2015, until December 1, 2015. A.P.'s records show that on December 1, 2015, she was diagnosed with "Streptococcal pharyngitis" (strep throat) and prescribed an antibiotic, amoxicillin. Pet. Ex. 3 at 83.

community. Tr. 72-73. Petitioner had experienced this with A.P.'s sister and she did not want to put herself through that again with A.P. Tr. 73. And for this reason, she did not take A.P. to the doctor when she had a dramatic change in behavior and did not report the dramatic change in her behavior to the physicians at the visits in December 2015. Tr. 72-73.

Moving forward to 2016, Petitioner took A.P. to Dr. Kee on May 6, where she reported that A.P. had anxiety and crying five days after the MMR vaccine. Tr. 74 (citing Pet. Ex. 3 at 20). Petitioner acknowledged that she did not report A.P.'s obsessive frustration with drawing or terror experiences to Dr. Kee at that visit. Tr. 74-75. The record reflected that A.P. had been fussy and sneezing the prior three days and developed urinary urgency. Id. (citing Pet. Ex. 3 at 20).

A.P. saw pediatric infectious disease specialist Dr. Balbi on May 19, 2016 and reported A.P.'s separation anxiety occurring the prior fall after her vaccinations. Tr. 76; see Pet. Ex. 3 at 87. Dr. Balbi's record stated that A.P.'s separation anxiety "did resolve after about [one] month." Tr. 76 (quoting Pet. Ex. 3 at 87). Petitioner disagreed that this note was accurate, testifying that she did not remember telling Dr. Balbi the separation anxiety resolved after one month. Id. Petitioner also disagreed that the onset of A.P.'s urinary urgency or sensitivity issues occurred in April 2016, as reflected by Dr. Balbi's records. Tr. 77 (citing Pet. Ex. 3 at 87).

Dr. Elice's initial visit with A.P. was July 12, 2016. Tr. 78. Dr. Elice's note stated, "Mom reports that some early symptoms started after the second MMR coincident with fall seasonal allergies. Separation was severe and lasted [one] month and then faded away, going back to her normal self." Tr. 79 (quoting Pet. Ex. 4 at 3). After reviewing Dr. Elice's note, Petitioner testified that she did not recall sharing that information. Id. Petitioner also testified that she told Dr. Elice that A.P. had obsessive, intrusive behaviors, sensory sensitivities, and urinary symptoms the prior fall, although this history was not included in Dr. Elice's records. Tr. 80-81.

Petitioner was called as a rebuttal witness at the hearing to address the severity of some of A.P.'s symptoms in response to Respondent's expert witness testimony. Petitioner described in more detail that when A.P. had obsessions, Petitioner and A.P. would perform a ritual of "walking [] around the home and [] doing a lot of checking behaviors." Tr. 214-15.

Also on rebuttal, Petitioner testified that Dr. Elice's diagnosis for A.P. is PANS although he uses the word PANDAS in his records. Tr. 220. Petitioner thought Dr. Elice used the diagnosis of PANDAS instead of PANS for insurance purposes, since PANS may not be covered by insurance. Id.

4. Summary of Petitioner's Emails to and from Dr. Michael Elice

At the hearing, Petitioner testified that she may have had an email exchange with Dr. Elice when A.P. became ill. Tr. 71, 81. Due to this testimony, Petitioner was ordered to file her email communications with Dr. Elice after the hearing. See Order dated Aug. 25 at 1; Pet. Ex. 46.

The first email, dated May 11, 2016, approximately eight months after the vaccination at issue, is from Petitioner to Dr. Elice and stated,

> I am looking for some direction as to what I can do for . . . [A.P.], age [four]. She is suffering terribly w[ith] her allergies and since then we are seeing severe and sudden sep[a]ration anxiety and urinary frequency. I took her to the pediatrician to have her urine checked and it came back clean. These issues are going on for about [two] weeks now and . . . her severe anxiety [] [is] interfering with her daily routine.
>
> . . . I'm thinking this may be allergy induced [PANS] flare but before I bring her to you, I'd like to run some immediate labs and see if we can help her. She's suffering terribly and it's heartbreaking to watch.

Pet. Ex. 46 at 2-3. Dr. Elice recommended testing and a visit to his office. Id. at 2.

The next email is dated September 12, 2016. Pet. Ex. 46 at 5. Petitioner described that A.P. was having "severe sep[a]ration anxiety before school." Id. Petitioner questioned whether mold in the home was contributing to A.P.'s anxiety. Id. She requested something to help with A.P.'s morning anxiety. Id. Dr. Elice suggested nighttime antihistamine and "[w]orst case scenario – she needs a low dose of some antianxiety meds." Id. Dr. Elice also recommended allergy testing, Benadryl, or hydroxyzine[26] or cyproheptadine, medications A.P.'s sister was taking, for sleep. Id. at 4. After several email exchanges, Dr. Elice recommended propranolol[27] 10 mg, a medication that had been administered to A.P.'s sister. Id. In a later email, Petitioner reported that propanol did not help A.P.'s anxiety. Id. at 11.

There were many email exchanges between Petitioner and Dr. Elice in January 2017. Pet. Ex. 46 at 7-12. On January 5, 2017, Petitioner notified Dr. Elice that A.P. had a respiratory virus with fever for ten days. Id. at 8. After the illness, A.P. regressed and her separation anxiety returned. Id. at 7-8. Petitioner wanted to try Acyclovir, an antiviral medication, and Dr. Elice responded that the antiviral was "worth a try." Id. at 8. A.P. started the medication on January 9. Id. at 7. On January 13, Petitioner emailed Dr. Elice stating A.P. continued to have "terrible sep[a]ration anxiety and obsessive thoughts." Id. at 11. On January 17, A.P. had a fever of 102.6° and "a terrible cough." Id. at 9. Petitioner questioned whether A.P. should be seen by her pediatrician, and if an antibiotic was prescribed, whether the antiviral should be discontinued. Id. A.P. was seen by her pediatrician, who Petitioner reported provided "no

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[26] Hydroxyzine is "a piperazine derivative with central nervous system depressant, antispasmodic, antihistaminic, and antifibrillatory actions." Hydroxyzine, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=23563 (last visited Feb. 6, 2024).

[27] Propranolol is "a nonselective beta-adrenergic blocking agent that lacks intrinsic sympathomimetic activity, decreases cardiac rate and output, [and] reduces blood pressure." Propranolol, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=41268 (last visited Feb. 6, 2024).

explanation for [A.P.'s] fever and cough." Id. at 10. Dr. Elice asked Petitioner to bring A.P. in to see him the following day. Id. On January 31, Petitioner advised that A.P.'s anxiety "seem[ed] to be dwindling" but "she still [woke] up in tears and ha[d] awful anxiety . . . before school." Id. at 12.

The next email, dated March 3, 2017, advised that one week before, A.P. had a stomach virus for 48 hours, but her illness was not followed by anxiety, OCD, or baby talk. Pet. Ex. 46 at 13. Instead A.P. had a stable mood. Id. Petitioner resumed giving A.P. supplements but was "hesitant to continue the [antibiotics] and metronidazole." Id. A.P. had been on metronidazole for three to four weeks and azithromycin for approximately two months. Id.

On May 17, 2017, Petitioner emailed Dr. Elice to let him know that A.P. was "tolerating her spring allergies much better," noting that "our hard work seems to be paying off." Pet. Ex. 46 at 14. However, in June, A.P. had "a huge increase in irritability, [OCD] – getting stuck on ideas and objects, intense meltdowns[,] and difficulty falling asleep." Id. at 15. Petitioner questioned whether A.P. had parasites or the problems were due to the weather pattern, and asked if she could start "metronidazole for [a] couple of weeks." Id. Petitioner checked and "found a new loose tooth," and promised to call if things worsened. Id.

The next email exchange was July 31, 2017, when Petitioner advised that A.P. was doing well and going to half day camp without having any separation anxiety. Pet. Ex. 46 at 17. Petitioner observed "minor flare ups if [A.P. was] over scheduled" or went "too long without eating or drinking." Id.

In September 2017, Petitioner reported that A.P. had frequent loose stools and questioned whether A.P. had *C. difficile*. Pet. Ex. 46 at 18. Dr. Elice asked Petitioner to give A.P. daily probiotics and to bring her in to be seen. Id. On October 2, 2017, Dr. Elice advised that A.P.'s stool was positive for *C. difficile*. Id. at 20. He ordered Metronidazole. Id. Subsequent emails in October 2017 relate to dosing, upset stomach, and vomiting. Id. at 21-22.

Moving forward to 2018, Petitioner and Dr. Elice emailed concerning school 504 forms,[28] and Petitioner asked Dr. Elice whether she could use the diagnosis of "[a]utoimmune [e]ncephalitis" instead of PANS, stating, "I think I will get their attention more [with] [autoimmune encephalitis]." Pet. Ex. 46 at 24. Dr. Elice approved the use of autoimmune encephalitis as the diagnosis, stating, "[t]hat's what [PANDAS] is after all." Id.

[28] Section 504 of the Rehabilitation Act of 1973 requires schools receiving federal financial assistance to "provide to students with disabilities appropriate educational services designed to meet the individual needs of such students to the same extent as the needs of students without disabilities are met." Protecting Students with Disabilities, U.S. Dep't Educ., Off. for C.R., https://www2.ed.gov/about/offices/list/ocr/504faq.html#skipnav2 (last modified July 18, 2023). This may be in the form of accommodations and/or other specialized services. Id. Qualified students may be those who have a "physical or mental impairment that substantially limits one or more major life activities." Id.

Other email exchanges in 2018 concern the present vaccine case. On March 27, 2018, Petitioner stated, "I've been doing a lot of research on vaccine injury and [a]utoimmune disorders. I am convinced this is what caused [A.P.'s] onset as we saw an explosion of [PANS] symptoms [one] week following her MMR and [v]aricella booster." Pet. Ex. 46 at 25. Petitioner asked if Dr. Elice would be willing to give a statement for the case, and Dr. Elice agreed to an appointment to discuss the issues. Id. In April 2018, A.P. had the flu but did not have "any flare ups in [PANS] symptoms." Id. at 27. Email exchanges in September 2018 related to medical exemptions from vaccinations. Id. at 28. In November, there was email correspondence regarding stool test results. Id. at 30. And another email exchange in November dealt with the difficulty A.P. had taking azithromycin tablets. Id. at 31-32.

In the Spring of 2019, there were emails about A.P. having hives following a bath. Pet. Ex. 46 at 33. Petitioner suspected that A.P. had Mast Cell Activation Syndrome ("MCAS")[29] due to "skin reactions/itchy rashes following warm baths." Id. A.P. received a steroid infusion, and afterward was "her normal self[,] playing again without intrusive thoughts." Id. at 35. Petitioner sent photos of A.P.'s rash, which she noted "look[ed] like scratch marks," and asked if A.P. had Bartonella.[30] Id. at 36. A.P. was improving with azithromycin. Id. There were also emails about the dosing of azithromycin. Id. 37-39. On May 2, A.P. was on a combination of azithromycin and hydroxyzine, and Petitioner reported that A.P. was "her happy relaxed self again." Id. at 40. In September 2019, A.P. took Augmentin for an infection. Id. at 42-43. Petitioner also emailed again about seeking exemptions from vaccines. Id. at 43-48.

The emails continued in 2020 and related to a flare in April 2020 after a cold sore. Pet. Ex. 46 at 49-50. In July 2020, Petitioner reported that A.P. had a flare associated with a loose tooth. Id. at 51. And in October 2020, Petitioner questioned whether A.P. wearing masks could be associated with flares. Id. at 52.

In February 2021, Petitioner informed Dr. Elice that A.P. was having a flare with "intense school refusal/anxiety." Pet. Ex. 46 at 53. She noted a wart on A.P.'s hand and questioned whether she needed an antiviral. Id. Dr. Elice ordered lab tests and recommended that A.P. come to the office after the tests were drawn. Id. at 54-55. In March, Petitioner reported that A.P. lost a tooth and all her symptoms disappeared after 24 hours. Id. at 56. There were additional emails in March and April about a rash and pollen. Id. at 56-60. In July 2021, there

[29] "Mast cell activation syndrome (MCAS) causes a person to have repeated severe allergy symptoms affecting several body systems. In MCAS, mast cells mistakenly release too many chemical agents, resulting in symptoms in the skin, gastrointestinal tract, heart, respiratory, and neurologic systems." Mast Cell Activation Syndrome, Genetic & Rare Diseases Info. Ctr., Nat'l Inst. Health, https://rarediseases.info.nih.gov/diseases/12981/mast-cell-activation-syndrome (last updated January 2024).

[30] It is not clear what bacterial species of Bartonella Petitioner is referring to; however, because it is mentioned in reference to a rash with a presentation of a scratch mark, she may be referring Bartonella henselae, a species that is the etiologic agent of cat-scratch disease. Pet. Ex. 46 at 36; Bartonella Henselae, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=60252 (last visited Feb. 6, 2024).

was correspondence regarding starting a detox protocol. Tr. 61-66. The last email was in May 2022, asking Dr. Elice to complete a form for A.P.'s 504 plan to ensure air conditioning in A.P.'s classroom to reduce pollen exposure. Tr. 67.

5. Letter from Cindy Russell from Abigail Bottoms Preschool

Ms. Russell was the director of the preschool A.P. attended from 2014 to 2016. Pet. Ex. 2 at 2. In her letter dated April 30, 2018, she stated that A.P. was a very happy child when she attended preschool at age three, during the 2014-2015 school year. Id. A.P. did not have any behavioral or emotional issues during that time. Id. About two weeks after the beginning of the school year in September 2015, however, A.P. had "a sudden and dramatic shift in her mood and behavior." Id. A.P. appeared "extremely distressed with a level of anxiety" that Ms. Russell had "rarely witnessed." Id. A.P. also had urinary frequency and began to "express sensory sensitivities." Id. "It was a struggle for about [four] to [five] months into the school year [until] her issues did seem to calm down a bit." Id. Her anxiety returned in April 2016, when A.P. "appeared to be suffering from seasonal allergies." Id. Ms. Russell concluded by stating that A.P.'s "presentation seemed to be so much more sudden and severe than any other child [she] [had] ever seen and . . . not characteristic of the child that first began attending [] preschool." Id. at 3.

D. Expert Reports

1. Petitioner's Expert, Dr. Marcel Kinsbourne[31]

a. Background and Qualifications

Dr. Kinsbourne is recognized as an expert in pediatric neurology. Tr. 90. In 1955, he obtained his B.M., B.Ch. from Oxford University Medical School, and he completed postdoctoral training through 1964 in the United Kingdom. Pet. Ex. 16 at 1. Thereafter, he obtained board certification and licensing in the United States and Canada and worked as a professor at various teaching institutions. Id. at 1-2. Dr. Kinsbourne has served and is currently serving on a number of editorial boards. Id. at 3-4. He has authored or co-authored more than 400 publications. Id. at 5-39. Dr. Kinsbourne is no longer a practicing physician. Tr. 90. He last saw patients in a hospital in the 1990s and has not regularly practiced medicine since 1995. Tr. 90, 107. Dr. Kinsbourne has never treated a patient with a PANS diagnosis, never diagnosed a patient with PANS, and never published on PANS. Tr. 108.

b. Diagnosis Opinion

Dr. Kinsbourne opined that A.P.'s diagnosis is PANS. Tr. 94. He testified that the evidence "in favor of the diagnosis of PANS" meets the standard of "medical probability." Tr. 104-06. He briefly described the history of the diagnosis and its relationship to a similar disorder

[31] Dr. Kinsbourne provided two expert reports and testified at the hearing. Pet. Exs. 15, 32; Tr. 3.

associated with streptococcal bacterial illness (PANDAS). Tr. 95-96. He explained that unlike PANDAS, PANS is not preceded by streptococcal illness. Tr. 96.

Regarding onset, Dr. Kinsbourne opined that within five to 15 days after receiving the MMR and varicella vaccinations, A.P. had an abrupt change in her behavior and personality. Tr. 91. She developed perfectionism, which is associated with OCD. Tr. 92. Gradually, this behavior faded and disappeared by the end of the year, and she did well until April 2016, when she had a relapse. Tr. 93. Dr. Kinsbourne based his opinions as to onset, specifically that A.P. developed symptoms, including OCD symptoms, seven to eight days after vaccination, on Petitioner's testimony at the hearing. Tr. 129, 131. He also relied on Ms. Russell's letter that stated onset of symptoms occurred two weeks after the start of the school year in September and the fact that the vaccinations were given one week into the school year. Tr. 131. He opined that A.P.'s OCD symptoms in September 2015 included waking up with fears, obsessions that became worse with age, and sensory sensitivities. Tr. 132-36.

Citing Swedo et al., Dr. Kinsbourne described the characteristics of PANS as including "anxiety, emotional lability and/or depression, irritability, aggression and/or oppositional behaviors, behavioral developmental regression, deterioration in school performance, sensory or motor abnormalities, somatic signs and symptoms including sleep disturbance, enuresis[,] and urinary frequency," and "obsessive-compulsive symptoms." Tr. 97 (citing Pet. Ex. 30 at 4 tbl.2). Dr. Kinsbourne, quoting records from Dr. Elice, testified that A.P. had these behaviors for one month, and then they faded away and she returned to her "normal self." Tr. 98-99 (quoting Pet. Ex. 4 at 3). A.P.'s aberrant behavior returned the following April when she had allergies. Tr. 99. Her condition was "relapsing and remitting." Tr. 100-01. Dr. Kinsbourne stated that A.P. was treated by Dr. Elice with anti-inflammatory measures, including intravenous immunoglobulin ("IVIG"). Tr. 101.

Dr. Kinsbourne agreed that A.P.'s medical records from Dr. Kee, Dr. Balbi, and Dr. Elice do not document that Petitioner reported A.P. suffered from intrusive thoughts, frustration with drawings, or perfectionistic tendencies. Tr. 114-15. He reasoned that the medical records were "not complete." Tr. 115. He agreed that Dr. Balbi ruled out the diagnosis of PANS and instead diagnosed A.P. with separation anxiety and allergies. Tr. 118. Dr. Kinsbourne agreed that A.P. had separation anxiety but he opined that she had many other symptoms as well. Id.

In his first expert report, Dr. Kinsbourne noted that on July 1, 2016, Dr. Elice documented A.P.'s chief complaint as "sudden onset separation anxiety" and "urinary frequency." Pet. Ex. 15 at 3 (quoting Pet. Ex. 4 at 4). Dr. Kinsbourne also noted that Dr. Elice recorded that A.P.'s "separation anxiety and other problem behaviors" reoccurred the following April (April 2016), during pollen season, and Dr. Elice noted A.P. had "PANDAS" symptoms. Id. (citing Pet. Ex. 4 at 3). At the hearing, he further agreed that Dr. Elice did not use the diagnosis of PANS for A.P. but instead documented PANDAS as her diagnosis. Tr. 117-18. Dr. Kinsbourne acknowledged that the criteria for PANS and PANDAS were different. Tr. 116-17.

During cross-examination, Dr. Kinsbourne agreed that Swedo et al. identified two threshold diagnostic criteria proposed for PANS: "abrupt, dramatic onset of OCD or severely restricted food intake." Tr. 109 (citing Pet. Ex. 30 at 4 tbl.2). He agreed that A.P. did not have

sudden onset of severely restricted food intake. Tr. 118. Dr. Kinsbourne also agreed that Dr. Elice did not diagnose A.P. with abrupt onset OCD. Tr. 118-19. He explained that a clearcut diagnosis of OCD would not be expected in a four-year-old child, where thinking is "concrete." Tr. 119. And he conceded that obsessions were not present at the beginning of A.P.'s condition.[32] Tr. 119-20.

Importantly, Dr. Kinsbourne agreed that there was no evidence of inflammation in A.P.'s laboratory test results in May 2016. Tr. 120. A.P. had many laboratory tests done in the years after her MMR vaccination and Dr. Kinsbourne conceded that none of them revealed any inflammation. Id.; see Pet. Ex. 15 at 2 (agreeing A.P.'s laboratory tests were negative except for "an elevated IgE, consistent with allergies").

Lastly, Dr. Kinsbourne opined that "both OCD and PANS are familial conditions, meaning that . . . this rare syndrome is based on some [] yet undiscovered genetic susceptibility which multiple family members can share." Tr. 224. Therefore, he asserted that because A.P. has a sibling with PANS, it is more likely that A.P. also has the condition. Id.

c. Causation Opinion

i. Althen Prong One

In his first expert report, Dr. Kinsbourne opined that neuroinflammation causes PANS and PANDAS, and that the neuroinflammation "could be the result of an immune reaction, perhaps by molecular mimicry, against surface epitopes of infectious organisms and vaccines, which overflows into the formation of antineuronal antibodies." Pet. Ex. 15 at 7; see also Pet. Ex. 32 at 6-8.[33]

At the hearing, however, Dr. Kinsbourne testified that he no longer held the above opinion about the mechanism of molecular mimicry and PANS. Tr. 125. When asked to explain the medical theory of how the MMR vaccine can cause PANS, Dr. Kinsbourne testified that "no one has a mechanistic theory of [] how anything can cause PANS." Tr. 125-26. He added that "we're still trying to find out . . . how this mechanism works." Tr. 126.

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[32] Dr. Kinsbourne changed his testimony on this point after Petitioner was called as a rebuttal witness. On rebuttal, Petitioner testified that A.P.'s behavior "checking and asking about the weather" began "[v]ery close to her onset if not at her onset." Tr. 217. Petitioner could not identify when A.P.'s behavior checking room to room began, but did recall this behavior "every flare subsequent to her onset." Tr. 216-17. After hearing that testimony, Dr. Kinsbourne opined these behaviors were "obsessive." Tr. 222. He explained that at four years old, A.P. "would exhibit behaviors and point[s] of view, but not put them together systematically," and because she subsequently displayed OCD symptoms, "there can't be any doubt that she was, in fact, obsessive-compulsive in her behavior and mentation." Tr. 223. He also changed his opinion and concluded A.P. met the "abrupt, dramatic onset of [OCD] or severely restricted food intake." Id.

[33] In his second report, Dr. Kinsbourne briefly referenced several studies that discussed the antineuronal antibodies. See Pet. Ex. 32 at 7-8.

In addition to being unable to offer an opinion about a mechanistic theory, Dr. Kinsbourne seemed to advocate "a less rigorous standard" than preponderance of the evidence. Tr. 105-06. He opined that there was no way to prove that the vaccine caused PANS, and thus, he opined it was "more reasonable and practical to adopt a less rigorous standard, in which case the abrupt nature of [] onset, the compatible time frame[,] and potentially the fact that . . . PANS seems to be autoimmune or . . . likely autoimmune and . . . to respond to immune modulation treatment" is "sufficient . . . to meet that standard." Tr. 106.

In his expert reports, Dr. Kinsbourne referenced medical literature, and he addressed some of the articles during the hearing. He noted that Cooperstock et al. reported that children with PANS may have flares following vaccinations. Tr. 131 (citing Pet. Ex. 18 at 9); see also Pet. Ex. 15 at 8. While Cooperstock et al. stated there could be "symptom flares after routine childhood immunization," they noted that such flares were "relatively uncommon, brief, and manageable with non-steroidal anti-inflammatory agents." Pet. Ex. 18 at 9.

Citing several studies, Dr. Kinsbourne posited there is evidence of neuroinflammation in PANDAS and PANS. Pet. Ex. 15 at 6-7. He cited Cutforth et al.[34] for the proposition that in PANDAS "there is strong evidence for neuroinflammation in the basal ganglia and thalamus[] from imagining studies." Pet. Ex. 15 at 6 (quoting Pet. Ex. 20 at 4). However, this reference was about patients with PANDAS thought to be caused by *Streptococcus pyogenes.* See Pet. Ex. 20. The paper did not discuss PANS or vaccines or suggest that vaccines can trigger the onset of either PANS or PANDAS.

Dr. Kinsbourne cited Kumar et al.[35] as reporting "underlying activated microglia-mediated neuroinflammation" in PANDAS. Pet. Ex. 15 at 6 (quoting Pet. Ex. 24 at 2). However, Dr. Kinsbourne somewhat overstated the findings of Kumar et al. In Kumar et al., the authors noted "[i]ncreased binding potential values, suggesting underlying neuroinflammation[,] were found in [the] bilateral caudate" in PANDAS patients. Pet. Ex. 24 at 5. However, they noted the study findings had limitations because children were not used as controls. Id. at 7. Further, patients with PANS were not studied.[36]

Dr. Kinsbourne also cited Calaprice et al., a survey study completed by parents of children with PANS. Pet. Ex. 32 at 4-5 (citing Pet. Ex. 33). Based on the survey, the most

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[34] Tyler Cutforth et al., CNS Autoimmune Disease After *Streptococcus Pyogenes* Infections: Animal Models, Cellular Mechanisms and Genetic Factors, 11 Future Neurology 63 (2016).

[35] Ajay Kumar et al., Evaluation of Basal Ganglia and Thalamic Inflammation in Children with Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infection and Tourette Syndrome: A Positron Emission Tomographic (PET) Study Using ^{11}C-[R]-PK11195, 20 J. Child Neurology 749 (2015).

[36] For additional concerns about this study, see Resp. Ex. A, Tab 18 at 8 (Harvey S. Singer, Autoantibody-Associated Movement Disorders in Children: Proven and Proposed, 24 Seminars Pediatric Neurology 168 (2017)).

common trigger reported was an infection. Id. (citing Pet. Ex. 33 at 11). The survey was sent to families in the PANDAS Network database and posted on the websites of the PANDAS network and the International Obsessive-Compulsive Disorder Foundation. Pet. Ex. 33 at 4. The surveys (698 in total) were completed by parents (mothers completed 95%, fathers completed 4%, and less than 1% were completed by caregivers or patients). Id. The authors acknowledged the limitations based on the survey methodology (lack of recall and bias). Id. at 12. They also noted there was no "clinical confirmation of diagnosis," no confirmation of "medical features," and the "symptom and episode severity ratings were based on participant interpretations." Id. On cross-examination, Dr. Kinsbourne agreed that the Calaprice et al. survey findings were "just really [] patient opinion." Tr. 127. He agreed that the study was "not that reliable." Id.

Further, in spite of the lack of medical studies confirming that PANS is an autoimmune illness, Dr. Kinsbourne described PANS as "[a]utoimmune encephalopath[y]," which "do[es] not attack the central nervous system as a whole, but [instead] diverse select areas in the [central nervous system], giving rise to distinctive complexes of behavioral deviations." Pet. Ex. 15 at 6. "The disinhibited areas (in striatum) give rise to apprehensive, irritable[,] and defensive behavior unregulated by higher level cortical inhibition." Id. He compared PANS to other "acute inflammatory autoimmune encephalopath[ies]" like acute disseminated encephalomyelitis ("ADEM") and neuromyelitis optica ("NMO"). Id. at 7; Pet. Ex. 32 at 6.

The medical literature that Dr. Kinsbourne cited, however, does not equate PANS with ADEM or NMO, or other autoimmune encephalopathies. ADEM "is an inflammatory demyelinating disease of the central nervous system." Pet. Ex. 22 at 2.[37] Pellegrino et al. explained that ADEM is generally attributed to "a post-infectious []etiology." Pet. Ex. 27 at 2. Mealy et al. defined NMO as a "relapsing autoimmune disease that preferentially targets the spinal cord and optic nerves, leading to paralysis and blindness." Pet. Ex. 26 at 2. While the articles discuss the rare association of these conditions to vaccination, they provide no information to suggest that these conditions are similar to PANS in their pathogenesis or mechanistic cause. Nor do these articles discuss PANS or PANDAS.

Continuing with the subject of autoimmunity, according to Dr. Kinsbourne, children with PANS have "low levels of immunoglobulins" and "autoantibodies," and thus, appropriate medical therapy may include "immunomodulatory treatment" including IVIG. Pet. Ex. 32 at 5-6

[37] William Huynh et al., Post-Vaccination Encephalomyelitis: Literature Review and Illustrative Case, 15 J. Clinical Neuroscience 1315 (2008). For a description of the abnormal focal signs and brain MRI findings of white matter lesions in ADEM, see Pet. Ex. 22 at 3. For a description of ADEM and other post-vaccination inflammatory central nervous system demyelinating illnesses mentioned by Dr. Kinsbourne, see Pet. Ex. 23 (Dijmitrios Karussis & Panayiota Petrou, The Spectrum of Post-Vaccination Inflammatory CNS Demyelinating Syndromes, 13 Autoimmunity Revs. 215 (2014)); Pet. Ex. 26 (Maureen A. Mealy et al., Vaccines and the Association with Relapses in Patients with Neuromyelitis Optica Spectrum Disorder, 23 Multiple Sclerosis & Related Disorders 78 (2018)); Pet. Ex. 27 (Paolo Pellegrino et al., Acute Disseminated Encephalomyelitis Onset: Evaluation Based on Vaccine Adverse Events Reporting Systems, 8 PLoS One 1 (2013)). PANS is not identified in the literature filed by either party as an inflammatory demyelinating central nervous illness.

(quoting Pet. Ex. 33 at 3). He cited an article by Frankovich et al.,[38] which described guidelines for the use of immunomodulatory treatment for PANS. See Pet. Ex. 35. Corticosteroids were recommended for moderate-to-severe cases and plasma exchange and IVIG were reserved for patients with extreme and life-threatening impairment. Id. at 3.

Other papers cited by Dr. Kinsbourne did not support the use of immunomodulatory therapy for PANS and PANDAS. Sigra et al.[39] performed a systematic review of studies and case reports of PANS and PANDAS as well as childhood acute neuropsychiatric symptoms ("CANS") and pediatric infection-triggered autoimmune neuropsychiatric disorders ("PITAND"). Pet. Ex. 39 at 2. The authors found there was "insufficient evidence to clearly propose any treatment for PANDAS and related disorders." Id. at 13. "[Their] findings indicate[d] there [was] no strong evidence to recommend treatment of . . . PANS . . . with antibiotics . . . [or] immunomodulation . . . ." Id. at 14. Williams et al.[40] reported the results of a double-blind comparison study to determine whether IVIG "lead to rapid and sustained symptom improvement" in 35 children with PANDAS. Pet. Ex. 41 at 2. The study "failed to demonstrate superiority of IVIG over placebo." Id.

On cross-examination, when questioned about Sigra et al. and Williams et al., Dr. Kinsbourne agreed that the science "is not available." Tr. 127. But he noted that Williams et al. was a small study and described the problem studying illnesses that are relapsing and remitting in nature. Tr. 127-28.

ii. Althen Prong Two

Dr. Kinsbourne testified that the cause of A.P.'s PANS was her familial predisposition (her sibling has the syndrome)[41] that was triggered by vaccines. Tr. 102. He believed that the

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[38] Jennifer Frankovich et al., Clinical Management of Pediatric Acute-Onset Neuropsychiatric Syndrome: Part II—Use of Immunomodulatory Therapies, 27 J. Child & Adolescent Psychopharmacology 574 (2017).

[39] Sofia Sigra et al., Treatment of PANDAS and PANS: A Systematic Review, 86 Neuroscience & Biobehavioral Revs. 51 (2018).

[40] Kyle A. Williams et al., Randomized, Controlled Trial of Intravenous Immunoglobulin for Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections, 55 J. Am. Acad. Child & Adolescent Psychiatry 860 (2016).

[41] Dr. Kinsbourne cited an article by Lewin et al. that reported on a study of PANDAS in identical siblings. Pet. Ex. 25 (Adam B. Lewin et al., Pediatric Autoimmune Neuropsychiatric Disorders Associated with *Streptococcus* in Identical Siblings, 21 J. Child & Adolescent Psychopharmacology 177 (2011)). Regarding PANDAS, the authors noted that since "[i]mmune deficiencies and autoimmune predisposition are reported to occur at increased frequencies among family members," it was "therefore possible that these susceptibilities could be at play in developing an autoimmune response to [Group A *Streptococcus*] as hypothesized in PANDAS." Id. at 5.

vaccines were the cause of A.P.'s PANS for four reasons. Tr. 102-03. First, the MMR is a live virus vaccine that evokes an immune response. Tr. 102-03. Second, onset occurred within five to 15 days of vaccination. Tr. 103. Third, "it came out of nowhere, suddenly." Id. And fourth, there was no alternative explanation. Id.

He agreed that A.P.'s labs showed no evidence of inflammation. Tr. 120. He also agreed that pollen has not been shown to be a trigger of PANS exacerbations. Tr. 122. Regarding whether loose teeth are associated with PANS, Dr. Kinsbourne suspected that it may be the stress of going to the dentist that triggered the autoimmune disorder. Id. He conceded, however, that "[there is] no decent epidemiology really [that is] rigorous associating things with PANS." Id. He "[could not] give an informed opinion" on whether mouth bacteria from loose teeth could trigger a PANS flare. Tr. 123. He also did not know whether pollen could have immune effects on the brain. Tr. 123-24.

In A.P., Dr. Kinsbourne assumed that the trigger of her PANS (the MMR vaccine) induced the event and without the trigger, "the whole sequence [would not] have happened." Tr. 124-25. He asserted "[t]here [was] no other potential cause" for A.P.'s PANS. Pet. Ex. 15 at 10.

Dr. Kinsbourne agreed that none of A.P.'s physicians attributed her condition to the MMR vaccine, and that they simply noted the temporal association between the vaccination and onset of symptoms. Tr. 128.

iii. Althen Prong Three

Dr. Kinsbourne testified that A.P. had an immune response within five to 15 days of her MMR vaccination. Tr. 103. This opinion is based on Petitioner's testimony that onset was seven to eight days after vaccination. Tr. 129. He opined that a seven-to-eight-day interval "is within the risk interval for MM[RV]."[42] Pet. Ex. 15 at 10.

Initially, he was unable to provide the outside time frame for onset of PANS following vaccination because "the literature . . . [does not] give [] a [] maximum time frame or any time frame." Tr. 129. But Dr. Kinsbourne agreed that if PANS symptoms began eight months following vaccination, onset would be outside a medically acceptable time frame within which to infer causation. Tr. 130. Ultimately he agreed the outside time frame is usually six weeks. Id.

Dr. Kinsbourne agreed that temporal proximity alone is "insufficient to establish causation." Tr. 128.

[42] A.P. received the MMR vaccination, not the combined MMRV vaccination. Pet. Ex. 3 at 10.

2. Respondent's Expert, Dr. Donald L. Gilbert[43]

a. Background and Qualifications

Dr. Gilbert is a board-certified neurologist with a special qualification in child neurology. Resp. Ex. B at 2. He received his M.D. from the University of Michigan Medical School in 1993, after which he completed an internship and residencies in pediatrics and child neurology at Johns Hopkins. Id. at 1. "Since 1998, [Dr. Gilbert] ha[s] been on the faculty in the division of Child Neurology at Cincinnati Children's Hospital Medical Center and in the Department of Pediatrics at the University of Cincinnati College of Medicine" as a professor of Pediatrics and Neurology. Resp. Ex. A at 1. During his career, he has been a site investigator on two intensive, prospective longitudinal studies of PANDAS funded by the National Institute of Health. Id. at 2. He also provides direct patient care, and many of the children he sees have psychiatric symptoms, including anxiety and OCD, which he has received certification for through the American Board of Psychiatry and Neurology. Id.; Resp. Ex. B at 2; Tr. 143, 202. In his clinical practice, he also sees autoimmune neurological diseases, including ADEM, multiple sclerosis, and NMO, and receives referrals from physicians and parents regarding whether a child has PANDAS or PANS. Resp. Ex. A at 2; Tr. 143. Along with treating patients with PANDAS and PANS, Dr. Gilbert has written and presented papers about these conditions. Resp. Ex. A at 2; Tr. 143-46. Overall, Dr. Gilbert has authored or co-authored over 100 peer-reviewed publications, several of which are on PANDAS and PANS and have been filed in this case. Resp. Ex. A at 2; Resp. Ex. B at 22-46; see Resp. Ex. A, Tab 6;[44] Resp. Ex. A, Tab 7;[45] Resp. Ex. A, Tab 13;[46] Resp. Ex. A, Tab 19.[47]

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[43] Dr. Gilbert provided two expert reports and testified at the hearing. Resp. Exs. A, C; Tr. 3.

[44] Donald L. Gilbert, Inflammation in Tic Disorders and Obsessive-Compulsive Disorder: Are PANS and PANDAS a Path Forward?, 34 J. Child Neurology 598 (2019).

[45] Donald L. Gilbert et al., A Pediatric Neurology Perspective on Pediatric Autoimmune Neuropsychiatric Disorder Associated with Streptococcal Infection and Pediatric Acute-Onset Neuropsychiatric Syndrome, 199 J. Pediatrics 243 (2018).

[46] James F. Leckman et al., Streptococcal Upper Respiratory Tract Infections and Exacerbations of Tic and Obsessive-Compulsive Symptoms: A Prospective Longitudinal Study, 50 J. Am. Acad. Child & Adolescent Psychiatry 108 (2011).

[47] Harvey S. Singer et al., Moving from PANDAS to CANS, 160 J. Pediatrics 725 (2012).

b. Diagnosis Opinion[48]

Dr. Gilbert opined that A.P. did not have PANS. Tr. 147. Instead, he believed A.P. suffered from an anxiety disorder. Tr. 165.

There are several reasons for Dr. Gilbert's opinion that A.P. does not have PANS. First, he opined that A.P. does not meet the diagnostic criteria for PANS, as described in Swedo et al. Tr. 158-63 (citing Pet. Ex. 30 at 4 tbl.2). The two major criteria required for the diagnosis of PANS are an abrupt, dramatic onset of OCD or severely restricted food intake, both of which Dr. Gilbert opined A.P. did not have. Tr. 158-59, 163; Pet. Ex. 30 at 4 tbl.2. Further, the DSM criteria for OCD must be met, and he opined A.P.'s behavior did not rise to the level of OCD as defined by the DSM criteria. Tr. 159, 163.

Second, Dr. Gilbert opined that A.P. had many diagnostic tests performed, and the tests revealed normal results and no evidence of inflammation. Tr. 165-67. Dr. Elice ordered a wide range of tests, including fecal fat tests, stool tests for parasites, blood tests of amino acid levels, test for mitochondrial illnesses, blood studies for viral and bacterial infections, specific tests for Lyme disease and mycoplasma, and blood tests for immune function (IgG, IgM, IgE, and IgA). Tr. 165-66. Dr. Gilbert opined that all the tests were normal, except for IgE, which was elevated due to A.P.'s allergies. Tr. 166. Dr. Gilbert disagreed with Dr. Elice's interpretation of A.P.'s laboratory studies because Dr. Elice compared a patient's result to the mean, and then described the variation from the mean as either an excess or a deficit. Id. Thus, even if the result was within the range of what is considered normal, if it deviated from the mean, Dr. Elice referenced it as "an excess or a deficiency." Id.

Third, Dr. Gilbert noted that none of A.P.'s treating physicians diagnosed her with PANS. Tr. 167. A.P. was seen by Dr. Elice beginning in July 2016. Id. The records do not show that he diagnosed her with PANS. Id. Ultimately, Dr. Elice documented that A.P. had PANDAS. Id. Dr. Gilbert disagreed with that diagnosis because there was no evidence that A.P. had a streptococcal infection before the onset of her condition. Id. Assuming that when Dr. Elice used the diagnosis of PANDAS in his records, he was applying the terminology loosely, Dr. Gilbert disagreed that it was appropriate to do so.[49] Tr. 167-68. Further, Dr. Elice did not show that the criteria for PANS were applicable. Tr. 167.

Overall, Dr. Gilbert opined that Dr. Elice ordered tests that were not medically indicated and interpreted the results inaccurately. Tr. 168. Dr. Gilbert opined that harm was induced by

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[48] Some of Dr. Gilbert's discussion and opinions fall outside the subject matter of this Decision. Therefore, only his opinions related to diagnosis and causation are discussed. For example, Dr. Gilbert offered opinions about Dr. Elice's care and treatment; however, Dr. Elice's care and treatment is not at issue, and therefore, is not discussed. See Resp. Ex. A at 8-12; Resp. Ex. C at 1, 6. Further, Dr. Gilbert discussed medical information about A.P.'s family members, which is not discussed due to confidentiality concerns. See Resp. Ex. A at 5-7.

[49] Dr. Gilbert agreed on cross-examination that some physicians use PANDAS and PANS interchangeably. Tr. 200.

this practice. Tr. 168-69. For example, Dr. Gilbert testified that Dr. Elice used antibiotics to treat non-existing infections, which caused A.P. to develop *C. difficile*. Id. The antibiotics decrease normal flora allowing growth of harmful bowel flora, which caused diarrhea and pain. Tr. 169.

Instead of PANS, Dr. Gilbert opined that A.P.'s symptoms "fit best under an umbrella of anxiety and not OCD." Tr. 170. A.P. was frightened when not with her primary caregiver, wanting her mother to be within sight, and she had urinary frequency and difficulty sleeping. Id. Although Dr. Gilbert deferred to a child psychologist or psychiatrist to make a specific DSM-V diagnosis, he believed an anxiety disorder was the appropriate diagnosis. Id.

c. Causation Opinion

i. Althen Prong One

Dr. Gilbert opined that there was no "basis in science," "no lab support," and no theory to explain how the MMR vaccine can cause PANS. Tr. 172-74. He further opined that there is "no scientific research linking any vaccine, particularly MMR, to PANS or to the symptoms of PANS, OCD, or severely restricted food intake." Tr. 174.

Further, Dr. Gilbert testified that if PANS was caused by the MMR vaccine, it would be an autoimmune disorder, and over time, science has not shown that PANS is autoimmune in nature. Tr. 175. He testified that since the Swedo et al. criteria have been published, there have been case reports and a number of studies, including animal model studies, but none have supported the conclusion that PANS is an autoimmune illness. Tr. 175-76. In support of his opinion, Dr. Gilbert cited Cellucci et al.,[50] which focused on pediatric autoimmune encephalitis. Resp. Ex. A at 12 (citing Resp. Ex. A, Tab 5). Cellucci et al. reflected the opinions and guidelines of the Autoimmune Encephalitis International Working Group, through the efforts of a subcommittee that reviewed relevant literature and obtained input from experts in the field. Resp. Ex. A, Tab 5 at 1.

Cellucci et al. defined autoimmune encephalitis as "inflammatory brain diseases." Resp. Ex. A, Tab 5 at 2. "Children with [autoimmune encephalitis] present with acute or subacute onset of neuropsychiatric symptoms due to an underlying abnormal immune response to the [central nervous system]." Id. "A number of different antibodies have been described in children with [autoimmune encephalitis]," but Cellucci et al. stated that not all children with autoimmune encephalitis "have a known autoantibody." Id. The recommended workup for suspected autoimmune encephalitis includes brain MRI; a number of different blood tests including tests for certain antibodies, serological tests for infections, antinuclear antibodies, and serum complement and immunoglobulin levels; lumbar puncture and cerebrospinal fluid testing; nasopharyngeal swab for viral testing; and electroencephalogram ("EEG"). Id. at 4 tbl.1. PANS

[50] Tania Cellucci et al., Clinical Approach to the Diagnosis of Autoimmune Encephalitis in the Pediatric Patient, 7 Neurology Neuroimmunology & Neuroinflammation 1 (2020).

is identified as a "[d]isease with immune mechanisms under review."[51] Id. at 9 tbl.5. The authors stated, "[i]f a patient with possible [autoimmune encephalitis] subsequently does not have positive antibodies or paraclinical testing for neuroinflammation, a diagnosis of [autoimmune encephalitis] is not supported." Id. at 9. Specifically, as for PANS and PANDAS, the authors stated that these conditions "lack robust biomarkers, [] pathogenesis remains disputed[,] . . . [and] most children with PANDAS or PANS would not fulfill the proposed pediatric [autoimmune encephalitis] criteria." Id. at 11.

In addition to referencing medical literature showing that PANS has not been classified as an autoimmune encephalitis, Dr. Gilbert also cited papers about the efforts to create diagnostic tests for PANS and the conflicting outcomes. For example, Shimasaki et al.[52] looked at two groups of PANS patients, one group of patients who were improving and one that was not getting better. Pet. Ex. 40 at 3. Dr. Gilbert testified that "this study purport[ed] to show that [there was] an association between the levels of the Cunningham panel blood tests and the symptoms of PANS."[53] Tr. 177-78. The study was flawed for several reasons, primarily because it was not a blind study. Tr. 178. Later studies did not support any association between the Cunningham blood tests and worsening symptoms in PANS. See, e.g., Resp. Ex. A, Tab 2 at 1 (noting "it remains unknown if any of the analytes in the Cunningham Panel can predict treatment response" and arguing "[t]he Cunningham Panel is an unreliable biological measure"); Resp. Ex. A, Tab 20 at 1 (finding "[n]o correlation . . . between clinical exacerbations and autoimmune markers" and "[n]o differences . . . between individuals with [PANDAS] with or without exacerbations triggered by streptococcal infections");[54] Resp. Ex. C, Tab 2 ("Clinical use of the Cunningham Panel for diagnosing PANS or PANDAS, or for monitoring symptom severity, is not supported by this study.").

Dr. Gilbert also found Calaprice et al. problematic because it was based on patient perception and there was no verification of the triggers or diagnoses. Tr. 178-79. Moreover, the

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[51] For comprehensive papers addressing the clinical controversy relative to PANDAS, and the "failure to confirm a definitive pathogenic immune process," see Resp. Ex. A, Tab 18, at 6-9; Resp. Ex. A, Tab 19.

[52] Craig Shimasaki et al., Evaluation of the Cunningham Panel in Pediatric Autoimmune Neuropsychiatric Disorder Associated with Streptococcal Infection (PANDAS) and Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS): Changed in Antineuronal Antibody Titers Parallel Changes in Patient Symptoms, 339 J. Neuroimmunology 1 (2020).

[53] For background and further explanation related to the Cunningham panel of tests, see Resp. Ex. A, Tab 2 (Susanne Bejerot and Eva Hesselmark, The Cunningham Panel Is an Unreliable Biological Measure, 9 Translational Psychiatry 1 (2019)); Resp. Ex. C, Tab 2 (Eva Hesselmark and Susanne Bejerot, Biomarkers for Diagnosis of Pediatric Acute Neuropsychiatric Syndrome (PANS) – Sensitivities and Specificity of the Cunningham Panel, 312 J. Neuroimmunology 31 (2017)).

[54] Harvey S. Singer et al., Clinical Exacerbations in Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections, 121 Pediatrics 1198 (2008).

population was not representative. Tr. 179. Dr. Gilbert noted that Dr. Kinsbourne agreed that the Calaprice et al. study was not reliable. Tr. 178.

Cooperstock et al. noted "symptom flares after routine childhood immunization . . . [were] relatively uncommon, brief, and manageable with nonsteroidal anti-inflammatory agents." Pet. Ex. 18 at 9. Dr. Gilbert disagreed that this reference provided reliable evidence that vaccines can cause PANS. Tr. 181.

In his expert reports, Dr. Kinsbourne compared PANS to other autoimmune illnesses such as ADEM, multiple sclerosis, and NMO, noting that because these can be triggered by vaccines, PANS could also be caused by vaccines. See Pet. Ex. 15 at 7-8; Pet. Ex. 32 at 6. Dr. Gilbert disagreed with this reasoning, both for the reasons described in Cellucci et al. and because in each of these other conditions there are objective manifestations of inflammation. Tr. 179-80; see Resp. Ex. 5 at 2, 11. For example, in ADEM, a diagnostic brain MRI will show inflammatory lesions, and there is no such objective evidence in PANS. Tr. 180.

In summary, Dr. Gilbert explained that "no studies have provided a specific mechanism" of causation for PANS. Resp. Ex. C at 1. The current consensus from the Autoimmune International Working Group in by Celluci et al. (2020) is that PANS is a "[d]isease with immune mechanism under review." Id. (quoting Resp. Ex. A, Tab 5 at 9 tbl.5). Because no specific mechanism has been identified and since PANS has not been determined to be an autoimmune condition, Dr. Gilbert opined that vaccine causation of PANS has not been established. Id.

ii. Althen Prong Two

Dr. Gilbert opined that A.P. does not have an autoimmune condition. Tr. 181. She underwent many diagnostic tests, and they did not reveal evidence of inflammation characteristic of an autoimmune condition. Id.; Resp. Ex. A at 3. Additionally, A.P. did not have evidence of either systemic or central nervous system inflammation. Resp. Ex. A at 3.

Further, Dr. Gilbert observed that A.P.'s "clinical presentation of situational . . . anxiety is not consistent with an autoimmune mechanism." Resp. Ex. A at 3. In support, Dr. Gilbert cited Graus et al.,[55] a position paper to establish guidelines for the diagnosis of autoimmune encephalitis by prominent neuroimmunologists in the field. Resp. Ex. A, Tab 9. The paper is the result of a process of review and updates by a panel of researchers with clinical expertise in autoimmune encephalitis. Id. at 2. Three levels of clinical evidence for autoimmune encephalitis were established: possible, probable without confirmation of autoantibody status, and probable with autoantibody status needed. Id. Although psychiatric symptoms were included in the diagnostic framework, they had to be accompanied by objective indices of

[55] Francesc Graus et al., A Clinical Approach to Diagnosis of Autoimmune Encephalitis, 15 Lancet Neurology 391 (2016).

neurological inflammation, either through abnormal cerebrospinal fluid or MRI abnormalities.[56] Id. at 3, 9.

iii. Althen Prong Three

Dr. Gilbert testified that there has not been a medically acceptable time frame established for the onset of PANS after a trigger. Tr. 183. He opined that currently, there is no science that addresses the issue. Id. Further, since Dr. Gilbert opined that A.P. does not have PANS, he found it difficult to "create a relevant time frame for a condition that lacks a mechanism and doesn't meet criteria" for its diagnosis. Tr. 183-84.

III. DISCUSSION

A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Hum. Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). Petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, Petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

In particular, a petitioner must prove that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface v. Sec'y of Health & Hum. Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999));

[56] The criteria for possible autoimmune encephalitis include at least one of the following: "[n]ew focal [central nervous system] findings," "[s]eizures not explained by a previously known seizure disorder," "[cerebrospinal fluid] pleocytosis (white blood cell count of more than five cells per mm^3)," or "MRI features suggestive of encephalitis." Resp. Ex. A, Tab 9 at 3. Criteria for the diagnosis of "autoantibody-negative but probable autoimmune encephalitis" include at least two of the following: "MRI abnormalities suggestive of autoimmune encephalitis," "[cerebrospinal fluid] pleocytosis, [cerebrospinal fluid]-specific oligoclonal bands or elevated [cerebrospinal fluid] IgG index, or both," or "[b]rain biopsy showing inflammatory infiltrates and excluding other disorders (eg, tumour)." Id. at 9.

see also Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). The received vaccine, however, need not be the predominant cause of the injury. Shyface, 165 F.3d at 1351. A petitioner who satisfies this burden is entitled to compensation unless Respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B). However, if a petitioner fails to establish a prima facie case, the burden does not shift. Bradley v. Sec'y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

"Regardless of whether the burden ever shifts to the [R]espondent, the special master may consider the evidence presented by the [R]espondent in determining whether the [P]etitioner has established a prima facie case." Flores v. Sec'y of Health & Hum. Servs., 115 Fed. Cl. 157, 162-63 (2014); see also Stone v. Sec'y of Health & Hum. Servs., 676 F.3d 1373, 1379 (Fed. Cir. 2012) ("[E]vidence of other possible sources of injury can be relevant not only to the 'factors unrelated' defense, but also to whether prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question."); de Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008) ("The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the [P]etitioner's evidence on a requisite element of the [P]etitioner's case-in-chief."); Pafford, 451 F.3d at 1358-59 ("[T]he presence of multiple potential causative agents makes it difficult to attribute 'but for' causation to the vaccination. . . . [T]he Special Master properly introduced the presence of the other unrelated contemporaneous events as just as likely to have been the triggering event as the vaccinations.").

B. Factual Issues

Petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding her claim. § 13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records).

Medical records, specifically contemporaneous medical records, are presumed to be accurate and generally "warrant consideration as trustworthy evidence." Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). But see Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d 1378, 1382 (Fed. Cir. 2021) (rejecting the presumption that "medical records are accurate and complete as to all the patient's physical conditions"); Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 538 (2011) ("[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance." (quoting Murphy v. Sec'y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991), aff'd per curiam, 968 F.2d 1226 (Fed. Cir. 1992))), recons. den'd after remand, 105 Fed. Cl. 353 (2012), aff'd mem., 503 F. App'x 952 (Fed. Cir. 2013). The weight afforded to contemporaneous records is due to the fact that they "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium." Id. To overcome the presumptive accuracy of medical records, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." Sanchez v. Sec'y of Health & Hum. Servs., No. 11-

685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing Blutstein v. Sec'y of Health & Hum. Servs., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)), mot. for rev. denied, 142 Fed. Cl. 247 (2019), vacated on other grounds & remanded, 809 F. App'x 843 (Fed Cir. 2020).

There are situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. Campbell v. Sec'y of Health & Hum. Servs., 69 Fed. Cl. 775, 779 (2006) ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); Lowrie v. Sec'y of Health & Hum. Servs., No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) ("[W]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." (quoting Murphy, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley, 991 F.2d at 1575.

Despite the weight afforded medical records, special masters are not bound rigidly by those records in determining onset of a petitioner's symptoms. Valenzuela v. Sec'y of Health & Hum. Servs., No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); see also Eng v. Sec'y of Health & Hum. Servs., No. 90-1754V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) (Section 13(b)(2) "must be construed so as to give effect also to § 13(b)(1) which directs the special master or court to consider the medical records (reports, diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them").

C. Causation

To receive compensation through the Program, Petitioner must prove either (1) that A.P. suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that A.P. suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano, 440 F.3d at 1319-20. Petitioner must show that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface, 165 F.3d at 1352-53).

Because Petitioner does not allege A.P. suffered a Table Injury, she must prove a vaccine A.P. received actually caused her injury. To do so, Petitioner must establish, by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. Petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be "legally probable, not medically or scientifically certain." Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994). Petitioner cannot

establish entitlement to compensation based solely on her assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether Petitioner is entitled to compensation, the special master shall consider all material in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 13(b)(1)(A). The special master must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in Petitioner's favor when the evidence weighs in her favor. See Moberly, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); Althen, 418 F.3d at 1280 (noting that "close calls" are resolved in Petitioner's favor).

Testimony that merely expresses the possibility—not the probability—is insufficient, by itself, to substantiate a claim that such an injury occurred. See Waterman v. Sec'y of Health & Hum. Servs., 123 Fed. Cl. 564, 573-74 (2015) (denying Petitioner's motion for review and noting that a possible causal link was not sufficient to meet the preponderance standard). The Federal Circuit has made clear that the mere possibility of a link between a vaccination and a petitioner's injury is not sufficient to satisfy the preponderance standard. Moberly, 592 F.3d at 1322 (emphasizing that "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury" does not equate to proof of causation by a preponderance of the evidence); Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359-60 (Fed. Cir. 2019). While certainty is by no means required, a possible mechanism does not rise to the level of preponderance. Moberly, 592 F.3d at 1322; see also de Bazan, 539 F.3d at 1351.

IV. DIAGNOSIS ANALYSIS

As Federal Circuit precedent establishes, in certain cases it is appropriate to determine the nature of an injury before engaging in the Althen analysis. Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010). Since "each prong of the Althen test is decided relative to the injury[,]" determining facts relating to the claimed injury can be significant. Id.

A.P. received her vaccination September 10, 2015. On that date, Dr. Kee noted that she was doing well and she had a normal developmental assessment and physical examination. After receiving her vaccination, A.P. was not seen by any health care provider for three months. During that three-month period of time, there are no contemporaneous records that document any abnormal behavior.

The earliest-in-time records are medical records from December 2015. On December 1, 2015, A.P. was seen by Dr. O'Neill for a sore throat. A rapid strep test was positive and A.P. was diagnosed with strep pharyngitis and prescribed an antibiotic. There is no documentation at that visit to suggest that A.P. had any behavioral abnormalities after her September 2015 MMR vaccination or that she currently had any behavioral problems.

Two weeks later, December 14, 2015, A.P. was seen by PA Fincke for a fever and diagnosed with a viral illness. No behavioral concerns were documented. On December 16,

2015, A.P. saw Nurse Lawton who diagnosed A.P. with acute suppurative otitis media of the left ear and a viral upper respiratory infection, and prescribed antibiotics. There were no issues with A.P.'s behavior noted.

The first documented report of behavioral concerns occurred on January 22, 2016, when A.P. was seen by Dr. Kee for fever, congestion, cough, and runny nose. Dr. Kee diagnosed A.P. with sinusitis and prescribed antibiotics. Dr. Kee documented "per [Petitioner] [MMR]/varivax had noticed then b[e]havior changes/irritable sister [has] autoimmune mom will call in summer for tit[ers]." Pet. Ex. 3 at 16.

A.P. returned to Dr. Kee on May 6, 2016, with complaints of urinary frequency, nasal congestion, and sneezing. At this visit, Dr. Kee wrote, "[a]nxiety OCD this week, mom showed me vide[o] re MMR had [anxiety] crying [five] days after vaccine" and "issues this week with dance[,] school, [and] crying." Pet. Ex. 3 at 20. This history documents that A.P. had anxiety and crying five days after vaccination. The period of anxiety is not described, but the note does not suggest that A.P.'s anxiety and crying behavior continued for any length of time or that it was ongoing. The note also establishes that "this week" A.P. had crying associated with dance class and school. Id. Dr. Kee's diagnosis was allergic rhinitis, urinary urgency, and behavioral issues. A.P. saw Dr. Kee again on May 12, and Dr. Kee's assessment was acute pharyngitis and urinary frequency. Dr. Kee did not document a diagnosis of separation anxiety or PANS at either visit.

A.P.'s initial consultation with Dr. Balbi, infectious disease specialist, was May 19, 2016. A.P.'s mother reported that A.P. "recently developed a severe separation anxiety and increased [urinary] urgency over the past three weeks." Pet. Ex. 3 at 87. A.P. also had sensitivity to sun and clothing. Regarding A.P.'s post-vaccination behavior, Petitioner reported that A.P. had separation anxiety the "fall of last year after receiving the . . . MMR booster[]. It did resolve after about a month." Id. Dr. Balbi emphasized that "this has all taken place over the past three weeks." Id. Dr. Balbi's records establish that A.P.'s separation anxiety resolved after about one month post-vaccination. Her separation anxiety and additional symptoms (urinary frequency and sun and clothing sensitivity) began three weeks before this visit, approximately the end of April 2016. Dr. Balbi diagnosed A.P. with "increased [urinary] frequency and separation anxiety." Id. at 88. He stated that "PANS is unlikely." Id.

Dr. Balbi next saw A.P. on June 9, 2016. In his note from that visit, Dr. Balbi opined A.P.'s history "was not consistent with [PANS]," and that blood work was also done to try to rule out PANS. Pet. Ex. 3 at 89. Blood work drawn the prior visit was all negative except IgE, which was elevated due to allergies. Dr. Balbi diagnosed A.P. with "improving separation anxiety and allergies." Id. at 90. Thus, the record shows that although he specifically considered PANS, Dr. Balbi did not diagnosis A.P. with PANS.

Email correspondence between Petitioner and Dr. Elice on May 11, 2016 establishes that A.P.'s behavioral issues had been "going on for about [two] weeks." Pet. Ex. 46 at 2. These behaviors included "severe and sudden sep[a]ration anxiety and urinary frequency." Id. Using this note, onset of severe and sudden separation anxiety began the end of April 2016.

In summary, the most contemporaneous records of the medical providers, including specialist Dr. Balbi, and an email written by Petitioner establish that A.P. had anxiety and crying five days after her MMR vaccination and had separation anxiety that lasted about one month. Petitioner did not seek treatment for A.P.'s behavior. A.P. received no diagnosis by any health care provider relative to her post-vaccination behavior.

Over six months later, approximately the end of April and/or the beginning of May 2016, A.P. had the onset of "severe and sudden" separation anxiety accompanied by other abnormal behaviors, including urinary frequency and sensitivity to sun and clothing. She was seen by Dr. Kee and Dr. Balbi. Dr. Kee did not provide a specific diagnosis related to A.P.'s behavior. Dr. Balbi considered PANS and did blood work to rule it out. He did not, however, diagnose PANS but did diagnose A.P. with separation anxiety.

Petitioner first communicated with Dr. Elice in May 2016, but A.P. was not seen by him until July 2016. In the email correspondence prior to A.P.'s first visit with Dr. Elice, Dr. Elice did not document a diagnosis for A.P. See Pet. Ex. 46 at 2. When Dr. Elice did see A.P. in July 2016, he diagnosed her with "allergic rhinitis." Pet. Ex. 4 at 9.

Dr. Elice did not diagnosis A.P. with PANDAS until January 18, 2017. A.P. had separation anxiety, urinary frequency, nocturnal awakening, phobias and worries, and food sensitivities. Examination noted severe anxiety, itching, "fe[lt] hot and complain[ed] her skin hurt[], ha[d] temperature regulation problems," "conjunctival edema," "periorbital edema," "[p]harnynx [was] [i]njected," "shoddy left anterior cervical node," "upper airway wheez[ing]," and "acute sinusitis." Pet. Ex. 4 at 34-41. Antibiotics were ordered.

Although the undersigned has fully considered the affidavit and testimony from Petitioner, and the letter by Ms. Russell, neither are trained health care providers. Further, this evidence is later in time than the records documented within the first year of the events in question. Some of the evidence from Petitioner and Ms. Russell contradicts what is in the medical records, particularly the testimony given by Petitioner on rebuttal. Given these inconsistencies, it is reasonable to give greater weight to the contemporaneous medical records than to affidavits and testimony. See Cucuras, 993 F.2d at 1528 (noting that "the Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight"); Doe/70 v. Sec'y of Health & Hum. Servs., 95 Fed. Cl. 598, 608 (2010); Stevens v. Sec'y of Health & Hum. Servs., No. 90-221V, 1990 WL 608693, at *3 (Cl. Ct. Spec. Mstr. Dec. 21, 1990) (noting that "clear, cogent, and consistent testimony can overcome such missing or contradictory medical records"); Vergara v. Sec'y of Health & Hum. Servs., No. 08-882V, 2014 WL 2795491, at *4 (Fed. Cl. Spec. Mstr. May 15, 2014) ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony.").

Other special masters have been faced with similar situations and found the contemporaneous medical records more persuasive than the affidavits and testimonies of lay witnesses. See, e.g., Rote v. Sec'y of Health & Hum. Servs., No. 90-036V, 1992 WL 165970, *5 (Cl. Ct. Spec. Mstr. July 1, 1992) (finding the lay witness testimony insufficient to overcome the weight of the contemporaneous medical records); Bergman v. Sec'y of Health & Hum. Servs.,

No. 90-1252V, 1992 WL 78671, *4 (Cl. Ct. Spec. Mstr. Mar. 31, 1992) (same); Daiza v. Sec'y of Health & Hum. Servs., No. 90-1188V, 1992 WL 59709, *4 (Cl. Ct. Spec. Mstr. Mar. 5, 1992) (same).

In summary, A.P. was evaluated by a number of different physicians, including an infectious disease specialist, and Dr. Elice, who specializes in the treatment of PANS/PANDAS. Based on the medical records of these physicians who evaluated A.P., the undersigned finds that A.P. did not have a PANS diagnosis after vaccination. Relative to her behavioral issues, in April/early May 2016, she was diagnosed with separation anxiety. She was not diagnosed with PANS. This finding is consistent with the opinions of both Dr. Kinsbourne and Dr. Gilbert, who agree that A.P. had separation anxiety. See Tr. 118, 169.

In conclusion, the undersigned finds that Petitioner has failed to show by preponderant evidence that A.P. had a diagnosis of PANS after vaccination.[57]

V. CAUSATION ANALYSIS

A. Althen Prong One

Under Althen prong one, Petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. Andreu, 569 F.3d at 1375; Pafford, 451 F.3d at 1355-56. Petitioner's theory of causation need not be medically or scientifically certain, but it must be informed by a "sound and reliable" medical or scientific explanation. Boatmon, 941 F.3d at 1359; see also Knudsen, 35 F.3d at 548; Veryzer v. Sec'y of Health & Hum. Servs., 98 Fed. Cl. 214, 257 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). If Petitioner relies upon a medical opinion to support her theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen, 618 F.3d at 1347 ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); Perreira v. Sec'y of Health & Hum. Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an "expert opinion is no better than the soundness of the reasons supporting it" (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

The undersigned finds Petitioner failed to provide preponderant evidence of a sound and reliable theory to explain how the MMR vaccination can cause PANS. The most important reason for this finding is Dr. Kinsbourne's concession at the hearing. On cross-examination, he testified that "no one has a mechanistic theory of [] how anything can cause PANS." Tr. 125-26. He added that "we're still trying to find out . . . how this mechanism works." Tr. 126. Thus, Dr. Kinsbourne conceded that he could offer no causal mechanism to explain PANS. This opinion is consistent with that of Dr. Gilbert. See Tr. 171-73 (explaining there is no basis in science and no theory to explain how the MMR vaccine can cause PANS).

[57] To the extent that the records reflect a PANDAS diagnosis, that diagnosis was not made until January 2017, around one-and-one-half years after the vaccination at issue.

Further, Dr. Kinsbourne failed to show that the MMR vaccine is associated with triggering PANS. He did not offer any evidence to show that the vaccine can trigger the onset of PANS. Only one article mentioned vaccines. Cooperstock et al. stated that there could be "flares" of PANS after routine vaccination, but such incidents were "relatively uncommon, brief, and manageable with non-steroidal anti-inflammatory agents." Pet. Ex. 18 at 9. This statement does not provide evidence of causation.

There is also a lack of preponderant evidence to show that PANS is an autoimmune disorder. As explained by Dr. Gilbert, if PANS was caused by the MMR vaccine, it would be an autoimmune disorder. To date, however, the science does not show that PANS is autoimmune. Dr. Gilbert cited Cellucci et al., which illustrated PANS does not meet the criteria for an autoimmune illness. Instead, PANS is a "[d]isease with immune mechanisms under review." Resp. Ex. A, Tab 5 at 9 tbl.5.

Dr. Kinsbourne offered opinions to the effect that PANS was like other autoimmune illnesses like ADEM and NMO. But these opinions were not supported by evidence. Findings from studies suggesting that ADEM and/or NMO may be associated with vaccines cannot be extrapolated to PANS without foundational information, including an understanding that the illnesses are similar in pathogenesis and mechanism. When evaluating whether petitioners have carried their burden of proof, special masters consistently reject "conclusory expert statements that are not themselves backed up with reliable scientific support." Kreizenbeck v. Sec'y of Health & Hum. Servs., No. 08-209V, 2018 WL 3679843, at *31 (Fed. Cl. Spec. Mstr. June 22, 2018), mot. for rev. denied, decision aff'd, 141 Fed. Cl. 138, aff'd, 945 F.3d 1362 (Fed. Cir. 2020). The undersigned will not rely on "opinion evidence that is connected to existing data only by the ipse dixit of the expert." Prokopeas v. Sec'y of Health & Hum. Servs., No. 04-1717V, 2019 WL 2509626, at *19 (Fed. Cl. Spec. Mstr. May 24, 2019) (quoting Moberly, 592 F.3d at 1315). Instead, special masters are expected to carefully scrutinize the reliability of each expert report submitted. See id.

Finally, there is one other relevant Vaccine Program case with a reasoned decision. See Castaneda ex rel. N.A.C. v. Sec'y of Health & Hum. Servs., No. 15-1066V, 2020 WL 3833076 (Fed. Cl. Spec. Mstr. May 18, 2020), mot. for rev. denied, 152 Fed. Cl. 576. Although decisions of other special masters are not binding, the undersigned generally agrees with the reasoning of her colleague. See Boatmon, 941 F.3d at 1358; Hanlon v. Sec'y of Health & Hum. Servs., 40 Fed. Cl. 625, 630 (1998), aff'd, 191 F.3d 1344 (Fed. Cir. 1999).

In Castaneda, the Special Master found that the minor child met the diagnostic criteria for PANS, but did not find preponderant evidence of causation, particularly as to Althen prong one. Castaneda, 2020 WL 3833076 at *21-31. The Special Master stated that "[t]hough inflammation continues to be a hypothesis for PANS causation, the mechanism for inflammation is yet unknown." Id. at *23. Petitioner in Castaneda advanced two causal theories: a proinflammatory cytokine theory and a molecular mimicry theory. Id. at *22-27. The cytokine theory was not developed and there was no literature or other evidence filed in support of it. Id. at *23-27. And at the hearing, the petitioner's expert seemed to abandon the molecular mimicry theory in favor of the inflammatory theory based on cytokines. Id. at *27. Regardless, the Special Master did not find molecular mimicry to be a viable theory due to the rapid onset of symptoms (30 hours)

post vaccination. Id. at *27, *29. Although the timing here differs from Castaneda, the undersigned agrees with the reasoning of the finding as to Althen prong one in Castaneda and finds it consistent with the finding here.

Thus, the undersigned finds Petitioner has failed to provide preponderant evidence with respect to the first Althen prong.

B. Althen Prong Two

Under Althen prong two, Petitioner must prove by a preponderance of the evidence that there is a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). "Petitioner must show that the vaccine was the 'but for' cause of the harm . . . or in other words, that the vaccine was the 'reason for the injury.'" Pafford, 451 F.3d at 1356 (internal citations omitted).

In evaluating whether this prong is satisfied, the opinions and views of the vaccinee's treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 ("[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" (quoting Althen, 418 F.3d at 1280)). Medical records are generally viewed as trustworthy evidence since they are created contemporaneously with the treatment of the vaccinee. Cucuras, 993 F.2d at 1528. While the medical records and opinions of treating physicians must be considered, they are not binding on the special master. § 13(b)(1)(B) (specifically stating that the "diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court").

Since Petitioner failed to prove Althen prong one, it follows that she cannot prove Althen prong two. However, even if Petitioner had proven Althen prong one, the undersigned finds Petitioner has failed to show by preponderant evidence that there is a logical sequence of cause and effect showing A.P.'s MMR vaccination caused her to develop PANS.

First, A.P.'s treating doctors did not attribute her illness to vaccination. Treating physician statements are typically "favored" as treating physicians "are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" Capizzano, 440 F.3d at 1326 (quoting Althen, 418 F.3d at 1280). However, no treating physician's views bind the special master, per se; rather, their views are carefully considered and evaluated. § 13(b)(1); Snyder ex rel. Snyder v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. 706, 746 n.67 (2009). "As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases." Welch v. Sec'y of Health & Hum. Servs., No. 18-494V, 2019 WL 3494360, at *8 (Fed. Cl. Spec. Mstr. July 2, 2019).

A.P. received her vaccination September 10, 2015. On December 1, 2015, A.P. was seen by Dr. O'Neill for a sore throat. A rapid strep test was positive and A.P. was diagnosed with strep pharyngitis and prescribed an antibiotic. There is no documentation at that visit to suggest

that A.P. had any behavioral abnormalities after her prior MMR vaccination in September. Further, there is no documentation that A.P. currently had any behavioral problems.

Two weeks later, on December 14, 2015, A.P. was seen by PA Fincke for a fever. She was diagnosed with a viral illness. Again, there is no documentation about behavioral concerns. On December 16, 2015, A.P. saw Nurse Lawton and was diagnosed with acute suppurative otitis media of the left ear and viral upper respiratory infection and prescribed antibiotics. Once again, there were no issues with A.P.'s behavior noted.

The first documented report of behavioral concerns was January 22, 2016, when A.P. was seen by Dr. Kee for fever, congestion, cough, and runny nose. Dr. Kee diagnosed A.P. with sinusitis and prescribed antibiotics. Dr. Kee documented "per [Petitioner] [MMR]/varivax had noticed then b[e]havior changes/irritable sister [has] autoimmune mom will call in summer for tit[ers]." Pet. Ex. 3 at 16. Although Dr. Kee documented Petitioner's report of behavior changes in association with vaccination, Dr. Kee did not suggest A.P.'s behavioral changes were caused by the MMR/Varivax vaccination.

On May 6, 2016, Dr. Kee saw A.P. for complaints of urinary frequency, nasal congestion, and sneezing. At this visit, Dr. Kee wrote, "[a]nxiety OCD this week, mom showed me vide[o] re MMR had [anxiety] crying [five] days after vaccine" and "issues this week with dance[,] school, [and] crying." Pet. Ex. 3 at 20. Again, although Dr. Kee documented what Petitioner reported about the crying after vaccination, Dr. Kee did not attribute A.P.'s anxiety or crying to the MMR vaccination.

About two weeks later, on May 19, 2016, A.P. was seen by Dr. Balbi, an infectious disease specialist. Petitioner reported that A.P. had separation anxiety after receiving the MMR vaccination. Although Dr. Balbi documented Petitioner's concerns, he did not offer an opinion that A.P.'s behavior was associated with her vaccination.

Lastly, Dr. Elice, an expert in PANS/PANDAS, saw A.P. beginning in July of 2016 and did not document any opinion that the MMR vaccination caused A.P.'s behavioral problems or any other illness.

In total, A.P. was seen by at least six different health care providers in the year after vaccination and none of them attributed A.P.'s behavioral problems to vaccination.

Second, A.P. had numerous diagnostic tests that did not reveal evidence of inflammation that would be seen if her condition was autoimmune or caused by vaccination. Dr. Kinsbourne conceded this point at the hearing. Although he used the diagnosis "autoimmune encephalitis," there is no objective evidence by MRI, lumbar puncture and cerebrospinal fluid testing, or EEG to support a diagnosis of encephalitis. Graus et al., for example, illustrated the point that A.P. did not meet the objective criteria for even possible autoimmune encephalitis because she did not have cerebrospinal fluid abnormalities or MRI abnormalities.

Third, there is not a logical sequence of cause and effect because A.P. did not have symptoms consistent with a diagnosis of PANS after vaccination. She was not diagnosed with

PANDAS until January 2017, around one-and-one-half years after vaccination, and long after the time frame for vaccine causation, as discussed in more detail in the diagnosis and Althen prong three sections.

For all these reasons, the undersigned finds that Petitioner failed to provide preponderant evidence of a logical sequence of cause and effect. Thus, Petitioner has failed to satisfy Althen prong two.

C. Althen Prong Three

Althen prong three requires Petitioner to establish a "proximate temporal relationship" between the vaccination and the injury alleged. Althen, 418 F.3d at 1281. That phrase has been defined as a "medically acceptable temporal relationship." Id. A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." de Bazan, 539 F.3d at 1352. The explanation for what is a medically acceptable time frame must also be consistent with the theory of how the relevant vaccine can cause the injury alleged (under Althen prong one). Id.; Koehn v. Sec'y of Health & Hum. Servs., 773 F.3d 1579, 1243 (Fed. Cir. 2014); Shapiro, 101 Fed. Cl. at 542; see also Pafford, 451 F.3d at 1358. Thus, prong three contains two parts. First, Petitioner must establish the "timeframe for which it is medically acceptable to infer causation" and second, Petitioner must demonstrate that the onset of the disease occurred in this period. Shapiro, 101 Fed. Cl. at 542-43.

Because Althen prong three is dependent on the medical theory required by Althen prong one, Petitioner's inability to meet her burden demonstrating how the MMR vaccine can cause PANS effectively precludes her from being able to meet his burden under the third Althen prong.[58] Thus, because the undersigned finds that Petitioner did not offer a sound and reliable theory of causation, she cannot demonstrate that A.P.'s condition arose in a medically acceptable timeframe pursuant to that theory. Even assuming that Petitioner satisfied Althen prong three, that alone would not satisfy Petitioner's overall burden of proof. See Veryzer v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 344, 356 (2011) (explaining that a "temporal relationship alone will not demonstrate the requisite causal link and that [P]etitioner must posit a medical theory causally connecting the vaccine and injury."); Moberly, 592 F.3d at 1323; Grant v. Sec'y of Health & Hum. Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) ("[A] proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury."). However, Petitioner's showing with respect to the third Althen prong is deficient.

A.P. received her MMR vaccination on September 10, 2015. On that date, Dr. Kee noted that she was doing well and she had a normal developmental assessment and physical examination. After receiving her vaccination, A.P. was not seen by any health care provider for three months. There are no contemporaneous records that document any abnormal behavior by A.P. during those three months.

[58] Additionally, there are independent reasons that the undersigned finds Petitioner has failed to prove Althen prong three as explained herein.

The earliest-in-time documents include medical records beginning December 2015. On December 1, 2015, A.P. was seen by Dr. O'Neill for a sore throat. There is no documentation at that visit to suggest that A.P. had any behavioral abnormalities after her prior MMR vaccination in September or that she currently had any behavioral problems. Two weeks later, December 14, 2015, A.P. was seen by PA Fincke for a fever and diagnosed with a viral illness. No behavioral concerns were documented. On December 16, 2015, A.P. saw Nurse Lawton. There were no issues with A.P.'s behavior noted.

The first documented report of behavioral concerns occurred on January 22, 2016, when A.P. was seen by Dr. Kee. Dr. Kee documented "per [Petitioner] [MMR]/varivax had noticed then b[e]havior changes/irritable sister [has] autoimmune mom will call in summer for tit[ers]." Pet. Ex. 3 at 16.

A.P. saw Dr. Kee on May 6, 2016 for complaints of urinary frequency, nasal congestion, and sneezing. At this visit, Dr. Kee wrote, "[a]nxiety OCD this week, mom showed me vide[o] re MMR had [anxiety] crying [five] days after vaccine" and "issues this week with dance[,] school, [and] crying." Pet. Ex. 3 at 20. This history documents that that A.P. had anxiety and crying five days after vaccination. The period of anxiety is not described, but the note does not suggest that A.P.'s anxiety and crying behavior continued for any length of time or that it was ongoing.

A.P. saw Dr. Balbi on May 19, 2016. A.P.'s mother reported that A.P. "recently developed a severe separation anxiety and increased [urinary] urgency over the past three weeks." Pet. Ex. 3 at 87. A.P. also had sensitivity to sun and clothing. Regarding A.P.'s post-vaccination behavior, Petitioner reported that A.P. had separation anxiety the "fall of last year after receiving the . . . MMR booster[]. It did resolve after about a month." Id. This note shows that A.P.'s separation anxiety resolved one month after vaccination.

On May 11, 2016, email correspondence between Petitioner and Dr. Elice establishes that A.P.'s behavioral issues had been "going on for about [two] weeks." Pet. Ex. 46 at 2. These behaviors included "severe and sudden sep[a]ration anxiety and urinary frequency." Id. Using this note, onset of severe and sudden separation anxiety began at the end of April 2016.

In summary, the contemporaneous records created by medical providers, including specialist Dr. Balbi, and emails written by Petitioner establish that A.P. had anxiety and crying five days after her MMR vaccination and separation anxiety that lasted about one month. Petitioner did not seek treatment for A.P.'s behavior during that month. The behavior later reappeared and by the descriptions provided by Petitioner, the separation anxiety was "severe and sudden," and accompanied by other abnormal behaviors, including urinary frequency and sensitivity to sun and clothing. Pet. Ex. 46 at 2. During this period of abnormal behavior, Petitioner reported A.P.'s behavior to Dr. Kee, Dr. Balbi, and Dr. Elice.

Based on the most contemporaneous records, the undersigned finds that onset of A.P.'s severe abnormal behaviors, which were severe enough to require medical attention, began in late April/early May 2016, as described above, more than six months after vaccination.

Dr. Kinsbourne opined that the outside limit for onset of a post-vaccination autoimmune illness would be six weeks. See Tr. 130. The onset of A.P.'s severe symptoms requiring medical attention far exceeded six weeks. Therefore, the onset is not consistent with vaccine causation.

Accordingly, the undersigned finds Petitioner failed to provide preponderant evidence of Althen prong three.

VI. CONCLUSION

The undersigned extends her sympathy to Petitioner and her minor child A.P. for the difficulties that A.P. has experienced as reflected in the record and the testimony of Petitioner. The undersigned's Decision, however, cannot be decided based upon sympathy, but rather on the evidence and law.

For the reasons discussed above, the undersigned finds that Petitioner has failed to establish by preponderant evidence that the MMR vaccination A.P. received caused her to develop PANS. Therefore, Petitioner is not entitled to compensation and the petition must be dismissed.

In the absence of a timely filed motion for review pursuant to Vaccine Rule 23, the Clerk of Court **SHALL ENTER JUDGMENT** in accordance with this Decision.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master